18

EPA'S PESTICIDE PROGRAM AND FOOD SAFETY REFORM

Y 4. G 74/7: EN 8/25

EPA's Pesticide Program and Food Sa...

HEARING

BEFORE THE

ENVIRONMENT, ENERGY, AND
NATURAL RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

OCTOBER 29, 1993

Printed for the use of the Committee on Government Operations

JUL 19 [illegible]

U.S. GOVERNMENT PRINTING OFFICE
78-496 CC
WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-044229-X

EPA'S PESTICIDE PROGRAM AND FOOD SAFETY REFORM

4. G 74/7: EN 8/25

's Pesticide Program and Food Sa...

HEARING

BEFORE THE

ENVIRONMENT, ENERGY, AND
NATURAL RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

OCTOBER 29, 1993

Printed for the use of the Committee on Government Operations

JUL 1 9

U.S. GOVERNMENT PRINTING OFFICE
78-496 CC WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-044229-X

COMMITTEE ON GOVERNMENT OPERATIONS

JOHN CONYERS, JR., Michigan, *Chairman*

CARDISS COLLINS, Illinois
GLENN ENGLISH, Oklahoma
HENRY A. WAXMAN, California
MIKE SYNAR, Oklahoma
STEPHEN L. NEAL, North Carolina
TOM LANTOS, California
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
JOHN M. SPRATT, JR., South Carolina
GARY A. CONDIT, California
COLLIN C. PETERSON, Minnesota
KAREN L. THURMAN, Florida
BOBBY L. RUSH, Illinois
CAROLYN B. MALONEY, New York
THOMAS M. BARRETT, Wisconsin
DONALD M. PAYNE, New Jersey
FLOYD H. FLAKE, New York
JAMES A. HAYES, Louisiana
CRAIG A. WASHINGTON, Texas
BARBARA-ROSE COLLINS, Michigan
CORRINE BROWN, Florida
MARJORIE MARGOLIES-MEZVINSKY, Pennsylvania
LYNN C. WOOLSEY, California
GENE GREEN, Texas
BART STUPAK, Michigan

WILLIAM F. CLINGER, JR., Pennsylvania
AL McCANDLESS, California
J. DENNIS HASTERT, Illinois
JON L. KYL, Arizona
CHRISTOPHER SHAYS, Connecticut
STEVEN SCHIFF, New Mexico
C. CHRISTOPHER COX, California
CRAIG THOMAS, Wyoming
ILEANA ROS-LEHTINEN, Florida
DICK ZIMMER, New Jersey
WILLIAM H. ZELIFF, JR., New Hampshire
JOHN M. McHUGH, New York
STEPHEN HORN, California
DEBORAH PRYCE, Ohio
JOHN L. MICA, Florida
ROB PORTMAN, Ohio

BERNARD SANDERS, Vermont (Independent)

Julian Epstein, *Staff Director*
Matthew R. Fletcher, *Minority Staff Director*

Environment, Energy, and Natural Resources Subcommittee

MIKE SYNAR, Oklahoma, *Chairman*

KAREN L. THURMAN, Florida
CAROLYN B. MALONEY, New York
JAMES A. HAYES, Louisiana
CRAIG A. WASHINGTON, Texas
EDOLPHUS TOWNS, New York

J. DENNIS HASTERT, Illinois
JOHN M. McHUGH, New York
DEBORAH PRYCE, Ohio
JOHN L. MICA, Florida

BERNARD SANDERS, Vermont (Ind.)

Ex Officio

JOHN CONYERS, JR., Michigan
WILLIAM F. CLINGER, JR., Pennsylvania

Sandra Z. Harris, *Staff Director*
James V. Aidala, *Professional Staff Member*
Elisabeth R. Campbell, *Clerk*
Charli E. Coon, *Minority Professional Staff*

CONTENTS

Page

Hearing held on October 29, 1993 1

Statement of:

- Goldman, Lynn, Assistant Administrator, Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency, accompanied by Michael R. Taylor, Deputy Commissioner for Policy, Food and Drug Administration, Health and Human Services 43
- Guerrero, Peter, Associate Director, Environmental Protection Issues, U.S. General Accounting Office, accompanied by J. Kevin Donohue, Assistant Director; Robert J. Tice, evaluator in charge; and Mark Trapani, evaluator 2
- Martin, John C., inspector general, U.S. Environmental Protection Agency, accompanied by Kimberly O'Lone, audit manager, northern division, Chicago office 18
- Rominger, Richard, Deputy Secretary, U.S. Department of Agriculture, accompanied by Larry Elworth, special assistant for pesticide policy 66
- Synar, Hon. Mike, a Representative in Congress from the State of Oklahoma, and chairman, Environment, Energy, and Natural Resources Subcommittee: Opening statement 1

Letters, statements, etc., submitted for the record by:

- Goldman, Lynn, Assistant Administrator, Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency: Prepared statement 47
- Guerrero, Peter, Associate Director, Environmental Protection Issues, U.S. General Accounting Office: Prepared statement 6
- Martin, John C., inspector general, U.S. Environmental Protection Agency: Prepared statement 21
- Rominger, Richard, Deputy Secretary, U.S. Department of Agriculture: Prepared statement 69

APPENDIX

Material submitted for the hearing record 101

EPA'S PESTICIDE PROGRAM AND FOOD SAFETY REFORM

FRIDAY, OCTOBER 29, 1993

HOUSE OF REPRESENTATIVES,
ENVIRONMENT, ENERGY,
AND NATURAL RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:23 a.m., in room 2154, Rayburn House Office Building, Hon. Mike Synar (chairman of the subcommittee) presiding.

Present: Representatives Mike Synar, Karen L. Thurman, Craig A. Washington, and John L. Mica.

Also present: Sandra Z. Harris, staff director; James V. Aidala, professional staff member; Elisabeth R. Campbell, clerk; and Charli E. Coon, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN SYNAR

Mr. SYNAR. Subcommittee will come to order. This morning we will welcome a new crew of players to the wonderful world of food safety.

After 12 years, the party in power has shifted, but I can assure you all in this room that the subcommittee's concerns remain the same.

We remain concerned that our great grandchildren will still hold hearings wondering when pesticide registration will be completed.

We remain concerned at missed deadlines, absent and misplaced priorities, and chronic shortages of money and authority have plagued this program and continue to do so.

We remain concerned that the rhetoric too often replaces reason, and that political posturing is preferred to meaningful reforms.

We remain committed as an oversight subcommittee to investigating how well or badly programs within our jurisdiction are doing, and whether there is a need to fix the blame or to fix the law, regardless of who is in charge.

This morning we will introduce ourselves and our concerns to a new team of officials faced with the duty of implementing our food safety laws. We wish them well, but we also put them on notice that newness in the job is no excuse for inaction.

It is already late to begin the reform process. Too much needs to be done too quickly to allow for much of a honeymoon. Almost 1 year ago we informed the new administration of the problems which would immediately face them in the pesticide program. Like it or not, the new administration has already had a long time to begin to address the needed reforms, and that is the measure by which we will judge this current program.

Vice President Gore hopes to reinvent government. This morning, we hope to hear how administration officials plan to reinvent the reregistration program. The administration's food safety plan announced in September is a credible start on the path toward reform.

I believe many elements of the package as described up to now must be precisely articulated so that we can better judge the effectiveness.

And as always, we reserve the possibility of offering complementary legislation so that in the end, that we can have the faith that the reforms we put in place now will in fact carry us into the next century with a pesticide regulation program that is finally in keeping with the modern age.

We are joined this morning by my colleague from Florida, Mrs. Thurman, for an opening statement.

Our first panel this morning will be Mr. Peter Guerrero, Associate Director of the Environmental Protection Issues of the U.S. General Accounting Office and the Honorable John C. Martin, inspector general of EPA.

If they would come forward. And John Martin is accompanied this morning by Kimberly O'Lone, audit manager.

Let me welcome you all. As you know, it is the policy of this subcommittee, in order not to prejudice past or future panels, to swear in all our witnesses. Do any of you have any objections to being sworn?

Anyone accompanying these witnesses who may be asked to testify please rise and be sworn.

[Witnesses sworn.]

Mr. SYNAR. First of all, before we begin, why don't we have Mr. Guerrero introduce who is with him today.

Mr. GUERRERO. Thank you, Mr. Chairman. Immediately to my left is Mark Trapani, principal investigator. Behind me also is another investigator, Bob Tice, and to my far left is Kevin Donohue, who represents some 12 years experience in this area.

Mr. SYNAR. As you know, the policy of the subcommittee is to submit your prepared testimony for the record. At this time we will hear from you, Mr. Guerrero, and we look forward to your comments.

STATEMENT OF PETER GUERRERO, ASSOCIATE DIRECTOR, ENVIRONMENTAL PROTECTION ISSUES, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY J. KEVIN DONOHUE, ASSISTANT DIRECTOR; ROBERT J. TICE, EVALUATOR IN CHARGE; AND MARK TRAPANI, EVALUATOR

Mr. GUERRERO. Thank you. Mr. Chairman, members of the subcommittee, we are pleased to be here today to discuss our work on EPA pesticide regulation and to relate this work to the administration's pesticide reform proposals.

Our testimony will be primarily based on recent GAO evaluations on the reregistration program, although as you know, we have issued more than 100 reports on the pesticide program over the past 25 years.

I will be pleased to discuss this larger body of work and to refer to it in questions and answers later. In summary, Mr. Chairman, we found that EPA will not be able to reregister all pesticides by 1998 as called for by the law. Instead, EPA estimates that it will not complete this program until the year 2006.

Second, EPA's progress in reregistering pesticides that are used on food has been substantially slower than expected. EPA has reregistered lower priority pesticides that present few food safety concerns. This low progress raises serious questions regarding the feasibility of the administration's proposal to review all pesticide tolerances within 7 years.

And third, EPA has understated the true costs of reregistration, and its proposed $20 million increase in user fees may prove to be insufficient.

Now, I would like to discuss some of these issues in greater detail.

After more than 20 years of data collection to support the reassessment of health and environmental effects of older pesticides, EPA has reregistered only 1 percent of the 20,000 older products currently in use. Moreover, most of these reregistered pesticides are not high priority food use pesticides, but are instead lower priority pesticides, such as dried blood and garlic that present few safety concerns.

EPA is still collecting data on most of the thousands of pesticide products currently used in agriculture and in the home, including most of the food use pesticides.

EPA's continuing delays in reregistering pesticides will be a roadblock to achieving the administration's pesticide policy initiatives. The administration's newly announced reforms call for EPA to establish a strong protective health-based standard for all pesticide residues in foods, and then to review all existing tolerances to make sure that they adhere to that standard.

However, tolerance reevaluations would, in most cases, follow reregistration, and EPA's current schedule for pesticide reregistration is behind.

Therefore, the goals of conducting these reevaluations of the tolerances within the 3 to 7 year timeframes envisioned by the proposals is unlikely to be met.

To reduce the public's exposure to the riskiest pesticides as soon as possible, it is imperative that EPA take action now to focus its efforts on the high priority food use pesticides that have the greatest potential to cause serious health problems.

Our report also recommends that the Congress consider amending FIFRA to require that EPA finish reregistering the highest priority food use pesticides before it reregisters lower priority ones.

I would like to make one final point concerning EPA's efforts to reregister pesticides. Such decisions must address current public health and safety concerns. However, another report on lawn care pesticides demonstrates this is not now the case. While EPA is reconsidering its long-held belief that individuals, and especially children, are not at risk from exposure to lawn care pesticides, the agency is nonetheless planning to reregister these pesticides using available data and techniques that may not fully address these concerns.

The administration's reform proposals would also establish a registration sunset provision. Under this provision, pesticide registrations would expire after 15 years unless EPA approves a new application which meets then current scientific safety standards.

Today, pesticide registrations have no fixed expiration date. While we have not evaluated EPA's rationale for establishing the 15-year period, we believe that a sunset provision would appropriately place the burden on registrants to identify and supply all the data that is needed to maintain their product registrations.

A sunset provision would also help ensure that pesticides would not remain on the market while health and safety concerns remain unanswered.

The administration's reform proposals would also strengthen the authorities of the food safety regulatory agencies to carry out their responsibilities under the law. It would increase the agency's inspection and regulatory authorities, and it would significantly increase civil and criminal penalties under FIFRA.

We fully support these proposed changes. As we reported in September 1992, the Food and Drug Administration's pesticide monitoring program does not prevent imported foods adulterated with illegal pesticide residues from reaching U.S. grocery shelves. We urge that strengthened legal authority to deter importers from marketing such foods and to penalize those that do.

Finally, the administration's proposal estimates a $20 million shortfall for reregistration through the end of 1997 and recommends that the shortfall be funded through increases in pesticide reregistration fees.

We believe, however, that this shortfall is likely to be greater than estimated. In our May report we questioned the adequacy of EPA's program cost estimates because EPA did not properly account for the additional data review costs and delays resulting from the high percentage of studies the agency had rejected and could reject.

In addition, EPA did not account for program costs beyond 1997 even though it had recognized that reregistration could not be completed by that date.

In conclusion, Mr. Chairman, we are encouraged that the administration has proposed many important initiatives for reforming pesticide regulation. Central to their success, however, is the timely completion of the pesticide reregistration program.

We believe that in view of the limited progress made to date, EPA should consider a risk-based approach to reregistration that would require it to address the highest priority food use pesticides before it reregisters lower priority pesticides.

More realistic cost estimates to complete this task are also needed. We would also note that regardless of whether the administration's reforms are enacted, and which ones are enacted, EPA needs to address critical management issues that have long limited its ability to regulate pesticides effectively.

Among these are resources insufficient to carry out its responsibilities, management information systems incapable of supporting this complex undertaking, and the lack of a consistent coordinated plan to reduce pesticide risk.

Mr. Chairman, that concludes my prepared remarks.

Mr. SYNAR. Thank you very much.

[The prepared statement of Mr. Guerrero follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Environment, Energy, and
Natural Resources, Committee on Government Operations,
House of Representatives

For release
on Delivery
Expected at
9:30 a.m. EDT
Friday
October 29, 1993

PESTICIDES

Reregistration Delays Jeopardize Success of Proposed Policy Reforms

Statement of Peter F. Guerrero,
Associate Director, Environmental Protection Issues,
Resources, Community, and Economic Development Division

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss our work on the Environmental Protection Agency's (EPA) reregistration of pesticides and to relate this work to the administration's proposal for reforming the federal regulation of pesticides and food safety. In addition, as you requested, we have compiled a listing of over 50 GAO reports and testimonies dealing with the regulation of pesticides that our Office has issued over the past 8 years. We have provided copies of the listing to the Subcommittee for inclusion into the record, as well as to EPA's new Assistant Administrator for Pesticides and Toxic Substances to assist her in becoming familiar with problems that we have identified.

We will base our testimony primarily on two reports that we recently issued on EPA's progress in reregistering pesticides. Our May 1993 report assessed the agency's reregistration of pesticides generally,[1] and our April 1993 report examined EPA's review of lawn care pesticides.[2] As you know, the EPA Administrator has recognized that completing reregistration is critical to achieving the administration's proposed reforms.

---

[1] Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

[2] Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects Are Uncertain, GAO/RCED-93-80, Apr. 6, 1993).

In summary, we found that

-- EPA will not be able to reregister all pesticide products by 1998, as required by the 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As of September 1993, EPA had reregistered only 250 of the 20,000 older pesticide products that are currently registered. EPA estimates that it may not complete reregistration until 2006. Furthermore, EPA's progress in reregistering pesticides used on food has been substantially slower than expected. Until it has reregistered these pesticides, it will not be able to review their tolerances, or allowable residues on food. Hence, it is unlikely that EPA will be able to meet the administration's goal of reviewing all existing pesticide tolerances within 7 years--and most high-risk pesticide tolerances within 3 years--after enactment of a food safety reform package. Finally, EPA has not included all costs in its estimate of the $20 million deficit it has projected to complete reregistration. A complete cost estimate is important because the administration has proposed to offset funding shortfalls in the reregistration program through increases in user fees.

-- EPA's schedule for reregistering lawn care pesticides has slipped, by as much as 4 years. But even after these pesticides have been reregistered, their safety may be uncertain. Until EPA has developed guidelines for assessing their effects on human health after they have been applied to lawns, the agency will not be able to ensure the safety of persons exposed to them--particularly of children, who may have more contact with treated lawns than adults. As you know, the administration's proposal gives high priority to protecting children from the risks associated with pesticides.

Before I discuss the results of our work in more detail, let me briefly review the chronology of EPA's reregistration program and summarize our findings in monitoring EPA's progress.

BACKGROUND

Federal efforts to reassess the safety of pesticides began in 1972, when the Congress amended FIFRA, recognizing that older pesticide products needed to be reassessed in accordance with modern scientific standards to ensure that their use did not harm human health or the environment. The Congress required EPA to complete reregistration within 4 years. EPA tried to develop a reregistration program but made little progress, in large part because it did not have sufficient resources. In 1975, we questioned whether EPA's program was adequately protecting the public from the hazards of pesticides.

In 1978, the Congress amended FIFRA to remove the deadline for completing reregistration because it was uncertain how many years this task would take. Instead, the Congress required EPA to reregister all pesticides as expeditiously as possible. In 1980, we noted EPA's slow progress, and in 1986, we determined that, at its current pace, reregistration would extend well into the 21st century. We suggested that the Congress consider setting deadlines and allowing EPA to collect user fees to fund additional efforts.

In 1988, the Congress again set a specific statutory timetable for completing reregistration, requiring EPA to reassess all active ingredients by 1997 and to reregister all products containing these active ingredients by 1998. It also allowed EPA to collect user fees to help support reregistration. In May 1993, we reported that reregistration had again fallen behind schedule.

In September 1993, the administration submitted a comprehensive pesticide policy reform plan to the Congress. This plan calls for EPA to regulate pesticides largely in accordance with risk and to take into account the sensitivities of subpopulations, such as children, when setting regulatory standards.

EPA MAY NOT REREGISTER ALL PESTICIDES UNTIL 2006

As we reported last May, EPA will not be able to reregister all pesticide products by the 1998 deadline. According to the agency's estimates, the program may not be completed until 2006.

After collecting data for over 20 years to reassess the health and environmental effects of older pesticides, EPA had, as of September 1993, reregistered only 250 of the 20,000 older products that are currently registered. Moreover, most of the reregistered pesticide active ingredients are not high-priority food-use pesticides but rather are generally lower-priority pesticides--such as garlic, dried blood, and putrescent egg solids--that present few safety concerns. EPA is still collecting data on most of the thousands of pesticide products that are currently used in agriculture and in the home, including most of the higher-risk food-use pesticides.

Reregistration has not proceeded on schedule because EPA did not take into account the complexity and magnitude of the reregistration task or the resources needed to conduct the program. Also, a large number of the studies submitted to support reregistration are insufficient to allow pesticides to be fully reassessed. In its program projections, EPA estimated that 10 percent of the required studies would be rejected as unacceptable. In fact, the rejection rate for unacceptable studies has been as high as 45 percent. These unacceptable studies will need to be redone, requiring years of additional work. In view of the limited progress that EPA has made in reassessing the risks of the highest-priority pesticides and the work that lies ahead to accomplish this objective, we continue to believe that the Congress may wish to consider requiring EPA to finish reregistering the highest-priority, food-use pesticides before it reregisters the lower-priority pesticides.

EPA's continuing delays in reregistering older pesticides will be a roadblock to achieving the administration's pesticide policy initiatives. The administration's newly announced reforms call for EPA to establish a strong, protective, health-based safety standard for pesticide residues in all types of food and then to review all existing tolerances to ensure that they meet the standard. The proposal also calls for EPA to reevaluate all existing pesticide tolerances within 7 years of the Congress's enacting a pesticide policy reform package. Under the proposal, tolerances for most of the highest-risk pesticides would be reevaluated within 3 years.

Delays in the reregistration program diminish the likelihood that EPA will be able to reevaluate all pesticide tolerances within 7 years. As you know Mr. Chairman, under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA determines which pesticides are allowed to remain as residues on individual food commodities, and in what amounts. The FFDCA tolerance program is linked to the

FIFRA reregistration program in that most of the data required for setting tolerances are obtained through the reregistration program. Hence, continuing delays in developing and reviewing these data, which may postpone the completion of pesticide reregistration until 2006, make it highly unlikely that EPA will be able to meet its schedule for reevaluating pesticide tolerances.

Under the administration's reform proposals, tolerance reevaluations would, in most cases, follow EPA's schedule for pesticide reregistrations. Therefore, timely reevaluations of pesticide tolerances largely depend upon timely reregistrations of pesticides. In view of EPA's prolonged schedule to complete pesticide reregistration, and a need to reduce the public's exposure to the riskiest pesticides as soon as possible, it is imperative that EPA focus its efforts on the high-priority food-use pesticides that have the greatest potential to cause serious health problems. Our report recommended that the Congress consider amending FIFRA to require that, except in unusual circumstances, EPA finish reregistering the highest-priority, food-use pesticides before it reregisters lower-priority pesticides.

The administration's reform proposals would also set into motion an important registration "sunset" provision. Under this provision, pesticide registrations would expire after 15 years unless EPA approved a registrant's new application meeting the then-current scientific standards for safety. Under the existing system, pesticide registrations have no fixed expiration dates. While we have not evaluated EPA's rationale for a 15-year period, we believe that a sunset provision would appropriately place the burden on registrants to identify and supply all the data needed to demonstrate that their registrations complied with current standards. A sunset provision would help ensure that unsafe pesticides were taken off the market and would enable EPA to schedule future pesticide product reregistrations efficiently.

The administration's reform proposals would also strengthen the authorities of the food safety regulatory agencies to carry out their responsibilities under law. It would improve inspection and laboratory audit authorities, significantly increase civil and criminal penalties for FIFRA violations, and enhance FDA's authority to recall violative goods and impose civil penalties. We fully support the intent of this proposal. As we reported in September 1992,[3] the Food and Drug Administration's pesticide monitoring program did not prevent imported foods adulterated with illegal pesticide residues from reaching U.S. grocery shelves. We recommended that the Congress consider strengthening the legal authority of the Secretary of Health and Human Services to penalize and deter importers from distributing pesticide-adulterated food.

---

[3] Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Finally, the administration's proposal estimates a $20 million shortfall in the reregistration program's budget through the end of 1997 and recommends that this shortfall be funded through increases in pesticide registrants' fees. While user fees might be one method of funding the shortfall, we believe that the shortfall is likely to exceed $20 million. In our May report, we questioned the adequacy of EPA's program cost estimate because, as we noted, the agency did not properly account for the additional data review costs and delays resulting from the high percentage of studies EPA has rejected and could reject in the future. In addition, EPA did not account for program costs beyond 1997, even though it recognized that reregistrations could not be completed by this date. As we recommended in our May 1993 report, the Administrator of EPA, in preparing an estimate of the costs and schedule for completing reregistration, should consider the additional review costs and delays that may result from the high percentage of studies the agency has rejected and may reject in the future.

LAWN CARE PESTICIDE REREGISTRATION FALLS FURTHER BEHIND

In our April 1993 report on the reregistration of lawn care pesticides, we reported that EPA's progress in reregistering the major lawn care pesticides had been delayed, principally because required study due dates had slipped, some by as much as 4 years. We also pointed out that even after reregistration, the safety of reregistered lawn care pesticides may still be uncertain because

EPA has not yet developed guidelines to assess the effects on human health of exposure to pesticides after they have been applied to lawns. In view of this uncertainty, we recommended that the Administrator of EPA should fully assess the health effects of post-application exposure to lawn care pesticides before reregistering pesticides for lawn uses. To accomplish this, EPA needs to place a high priority on developing the testing and assessment guidelines for post-application exposure.

Our recommendation in the lawn care pesticide reregistration report is consistent with the administration's proposal to improve the analysis of exposure to pesticides. Our report noted that in light of increasing congressional scrutiny of alleged pesticide poisonings, EPA is reevaluating its long-held view that homeowners and their families do not risk developing health problems from exposure to lawn care pesticides. In particular, EPA is concerned about the persistence of these pesticides in the environment and about their potential effects on children, who may have more contact with treated lawns than adults. We pointed out that, despite these concerns, the agency was planning to continue to reregister lawn care pesticides using available methodologies to assess the effects of exposure while it developed new post-application exposure testing and assessment guidelines, which the agency estimates will not be available until 1997.

Mr. Chairman, I would to close by stating that we are encouraged that the administration has proposed many important initiatives for reforming the regulation of pesticides. We agree with the Administrator of EPA that the timely completion of the reregistration review program is critical to the administration's efforts to fully assess and appropriately regulate pesticide risks. This concludes our prepared remarks. We would be pleased to answer any questions you may have.

(160244)

Mr. SYNAR. Mr. Martin.

STATEMENT OF JOHN C. MARTIN, INSPECTOR GENERAL, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY KIMBERLY O'LONE, AUDIT MANAGER, NORTHERN DIVISION, CHICAGO OFFICE

Mr. MARTIN. Thank you, Mr. Chairman, and other members of the subcommittee, I am here today to discuss our audits of two aspects of EPA's pesticides program, labeling and the special review process.

Labeling and special reviews are important components of the overall pesticide program. Both help to protect the public and the environment from any harmful impacts of pesticides.

But there are other crucial components, such as registration, that make up a complete, successful program. Let me tell you today about our most recent audits in these two areas. After EPA registers a pesticide, it may find that the pesticide might cause unreasonable risks. If this occurs, EPA may conduct a special review.

The purpose of the special review is to weigh the risks and the benefits of a pesticide's use and determine whether the pesticide should continue to be used. Over the years, Congress and GAO have criticized EPA about how long special reviews take.

In our July 1993 report we discussed how EPA's approach to conducting special reviews had changed over the past several years because the agency had recognized that special reviews took too long. So, since 1988 EPA has not started the regulatory special review process for any pesticide.

Instead of using special reviews when concern about the risks became known, EPA has begun using alternatives to reduce these risks. The primary alternative has been to negotiate with the registrants to discuss options, including even canceling or modifying a pesticide's registration. Compared to the special review process, negotiations have reduced the time it takes to address risks.

Our primary concern about EPA's new approach of using negotiations was the lack of public involvement. Throughout the special review process, which is set out in regulations, there is an emphasis on public involvement. This need for involvement was emphasized in a 1984 settlement agreement with the National Resources Defense Council. However, EPA has moved from the special review to, primarily, negotiations, but has no guidelines on how to conduct them or how to involve the public.

The lack of public involvement can adversely affect EPA decisions. For example, during negotiations on the pesticide parathion, registrants and EPA agreed that existing stocks of this pesticide could be used through 1991. However, EPA later found out from users that there were significantly more amounts of the pesticide available than the registrants had described. Because users were not involved in the decisionmaking process, EPA did not get this information until after the agreement was negotiated. EPA had to revise the agreement reached to allow the additional pesticide to be used.

We also found that EPA had few guidelines for interpreting and applying the regulations as to when a pesticide should be placed in special review. For example, the regulations state that EPA can start a review when the use of the pesticide may pose a serious acute injury to humans or domestic animals. There is no further guidance on what this means.

Guidelines are needed to help program personnel determine when a pesticide meets the criteria for special review. Without guidelines, EPA may not promptly start special reviews or consider risk reduction negotiations with the registrants.

In response to our July 1993 report, EPA has taken a number of very positive actions. For example, the agency formed a work group to review past negotiations. The work group will define what is expected when negotiating risk reductions, how it is most effectively achieved, and what options are available for public involvement. The work group's efforts will help define the negotiation process and ensure continued involvement in EPA decisions.

EPA also agreed with us that guidelines are needed for applying criteria for when to initiate a special review. When we began our audit, EPA had begun working on developing such guidelines. However, the pesticide program officials told us that because of budget constraints, the activity was not funded in 1993 but they hoped to fund the activity in 1994.

Before EPA registers a pesticide it must determine that the label complies with the requirements of the law, and that the pesticide will not pose an unreasonable risk to humans or the environment. The decision to register a pesticide is based on EPA's evaluation of the scientific data in toxicity studies that registrants provide. EPA determines what precautionary statements the label needs to include based on these studies.

Although toxicity studies may exist, EPA officials could not find them for over one-third of the 95 pesticides we reviewed in 1992. In many other cases, the pesticides, or similar pesticides, were registered before EPA began requiring such studies. Without these studies, EPA's assurance that the pesticides' labels contained correct, complete warning statements was diminished.

According to program officials, the "missing" studies will be obtained during reregistration. However, as this subcommittee is aware, reregistration is not expected to be completed for many years. Until then, there is no way to verify back to studies that the correct precautionary statements are on pesticide labels.

Another concern we found was that many of the labels we reviewed did not contain all the required precautionary statements. For example, some were missing warning language about the potential harm if the pesticide was absorbed through the skin, or did not contain correct statements on restrictions. Others did not include instructions on what to do if the pesticide got into the user's eyes.

When a pesticide registrant is seeking to market a product, EPA must review and approve the label. If the label does not include all the necessary precautionary statements, EPA requires the registrant to correct it. But once EPA directs these changes, the agency does not always ensure that the corrections are actually made.

We found cases where registrants did not make the changes requested. For example, in one case, one where the label should have said "causes irreversible eye damage."

In response to our September 1992 report, the agency did implement a number of improvements in the labeling program. For example, EPA began organizing all new toxicity studies to better support specific registrations and completed a system for tracking and analyzing incident reports. The agency said it would take other actions to resolve the many concerns we identified.

However, EPA's progress to date is mixed. A few months ago we followed up on our labeling report and our 1991 report on inert ingredients in pesticides.

EPA had made significant progress in completing corrective actions on the labeling report. For example, EPA program officials corrected the inaccurate labels we identified. They collected and disseminated a package of current labeling policies to appropriate branches to ensure that all reviewers had the same instructions. The other two items were scheduled for completion by the end of 1993.

However, EPA still had not completed many of the corrective actions to resolve the problems we identified in our inert ingredients report.

One example of delayed corrective actions is the area of potentially toxic inert ingredients. The program planned to complete its review on the available data on these inert ingredients early in 1993. This has now been delayed until at least the middle of 1995.

According to the Acting Assistant Administrator at the time we recently discussed this, the main reason for the delay was lack of funding. EPA requested funding for the inert program in 1992 and 1993, but the budget suffered substantial cuts. Without adequate funds, the then Acting Assistant Administrator told us the agency expects to make slow progress in this area. So, in conclusion, for over 20 years, EPA has been struggling with tough scientific and public policy issues. For the last few years my office has been reviewing the pesticides program and we have seen progress on some of our recommendations.

Other issues discussed in our reports require long-term solutions, and I know the new Assistant Administrator, Lynn Goldman, is going to address these issues in the area of public concerns that they relate to.

Thank you.

Mr. SYNAR. Thank you very much, Mr. Martin.

[The prepared statement of Mr. Martin follows:]

TESTIMONY OF JOHN C. MARTIN
INSPECTOR GENERAL
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON THE ENVIRONMENT, ENERGY, AND NATURAL RESOURCES
OF THE COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

October 29, 1993

Good morning Mr. Chairman and members of the subcommittee. I am here today to discuss our audits of certain aspects of EPA's pesticide program -- the labeling of pesticides, and the special review process.

Labeling and special reviews are important components of the overall pesticide program. Both of them help protect the public and the environment from any harmful impacts of pesticides. But there are also many other crucial components, such as registration, that make up a complete, successful program. In fact, in July 1992 I testified before this subcommittee on another aspect of the pesticide program -- how EPA addresses inert ingredients. Today I will discuss what our two most recent audits found, and what the Agency has been doing to correct the problems.

THE PESTICIDES SPECIAL REVIEW PROCESS

After EPA registers a pesticide, it may find that the pesticide might cause unreasonable risks. If this occurs, EPA may conduct a special review. The purpose of the special review is to weigh the risks and benefits of a pesticide's use and determine whether the pesticide should continue to be used. Over the years, Congress and GAO have criticized EPA about how long special reviews take.

Current Concerns About the Process

In our July 1993 report we discuss how EPA's approach to conducting special reviews had changed over the past several years because the Agency had recognized that the special review process took too long. So, since 1988 EPA has not started the regulatory special review process for any pesticide. Instead of using special reviews when concern about the risks became known, EPA has begun using alternatives to reduce these risks. The primary alternative has been to negotiate with registrants to discuss options, including even canceling or modifying a pesticide's registration. Compared to the special review process, negotiations have reduced the time it takes to address the risks.

Our primary concern about EPA's new approach of using negotiations was the lack of public involvement. Throughout the special review process, which is set out in regulations, there is an emphasis on public involvement. This need for public involvement was emphasized in a 1984 settlement agreement with the National Resources Defense Council. However, EPA has moved from the special review process to, primarily, negotiations, but has no guidelines for how to conduct them or for involving the public.

The lack of public involvement can adversely affect EPA decisions. For example, during negotiations on the pesticide parathion, registrants and EPA agreed existing stocks of the pesticide could be used through December 31, 1991. However, EPA later found out from users that there were significantly more amounts of the pesticide available for use than the registrants had described. Because users were not involved in the decision making process, EPA did not get this information until after the agreement was negotiated. EPA had to revise the agreement reached with the registrant to allow the additional pesticide to be used.

We also found that EPA had few guidelines for interpreting and applying the regulations as to when a pesticide should be placed in special review. For example, the regulations state that EPA can start a special review when the use of a pesticide "may pose a risk of serious acute injury to humans or domestic animals." There is no further guidance on what this means.

Guidelines are needed to help program personnel determine when a pesticide meets the criteria for special review. Without guidelines, EPA may not promptly start special reviews or consider risk reduction negotiations with registrants. For example, EPA waited 10 years to start a special review of carbofuran because it did not have guidelines for evaluating the adverse effects carbofuran presented. EPA started a special review of carbofuran in 1985 because the pesticide was highly toxic to birds. However, EPA was aware of bird kill incidents related to carbofuran use as early as 1974. According to pesticide program staff, the special review was delayed because EPA did not have the criteria to place a pesticide in special review for these environmental effects.

EPA Actions

In response to our July 1993 report, EPA has taken a number of very positive actions. For example, the Agency formed a workgroup to review past negotiations. The workgroup will define what is expected when negotiating risk reductions, how is it most effectively achieved, and what options are available for public involvement. The workgroup's efforts will help define the negotiation process and ensure continued public involvement in EPA decisions.

EPA also agreed with us that guidelines are needed for applying criteria for when to initiate a special review. When we began our audit, EPA had been working on developing such guidelines. However, pesticide program officials stated that because of budget cuts, the activity was not funded in 1993. The program hopes to fund this activity in 1994.

PESTICIDES LABELING

Before EPA registers a pesticide, it must determine that the label complies with the requirements of the law, and the pesticide will not pose an unreasonable risk to humans or the environment. The decision to register a pesticide is based on EPA's evaluation of the scientific data in toxicity studies that registrants provide. EPA determines what precautionary statements the label needs to include based on these studies.

Concerns With Labeling

Although toxicity studies may exist, EPA officials could not find them for over one-third of the 95 pesticides we reviewed in 1992. In many other cases, the pesticides, or similar pesticides, were registered before EPA began requiring such studies. Without these studies, EPA's assurance that the pesticides' labels contained correct, complete warning statements was diminished.

According to program officials, the "missing" studies will be obtained during reregistration. However, as this subcommittee is aware, reregistration is not expected to be completed for many years. Until then, there is no way to verify back to studies that the correct precautionary statements are on pesticide labels.

Another concern we found was that many of the labels we reviewed did not contain all of the required precautionary statement language. For example, some were missing warning language about the potential harm if the pesticide was absorbed through the skin, or did not contain the correct statements on use restrictions. Others did not include instructions in what to do if the pesticide gets into the user's eyes.

When a pesticide registrant is seeking to market a product, EPA must review and approve its label. If the label does not include all the necessary precautionary statements, EPA requires the registrant to correct it. But once EPA directs these changes, the Agency does not always ensure they are actually made. We found cases in which registrants did not make the changes EPA requested. In one case the label was missing the statement "Causes irreversible eye damage."

Finally, registrants must send EPA "incident reports" whenever they obtain information that a pesticide may cause unreasonable adverse effects on humans or the environment. Many of the reports in EPA's files describe very serious incidents, including human and animal deaths. However, at the time of our review EPA was not centrally collecting, organizing, and following up on incident reports it received. Shortly before we issued our report, EPA completed a system for tracking and analyzing these reports which may correct many of the deficiencies we found.

EPA Actions

In response to our September 1992 report, the Agency implemented a number of improvements in the labeling program. For example, EPA began organizing all new toxicity studies to better support specific registrations and completed a system for tracking and analyzing incident reports. The Agency stated it would take yet other actions to resolve the remaining concerns we identified.

EPA'S PROGRESS TO DATE IS MIXED

A few months ago we followed up on our labeling report and our 1991 report on inert ingredients in pesticides.

EPA had made significant progress in completing corrective actions on our labeling report. Agency officials have completed their promised corrective actions in response to 7 of our 9 recommendations. For example, program officials corrected the inaccurate labels we identified, and collected and disseminated a package of the current labeling policies to the appropriate branches to ensure that all reviewers had the same instructions. The other two were scheduled for completion by the end of December 1993.

However, EPA had still not completed many of the corrective actions to resolve the problems identified in our report on inert ingredients. The problems we identified in the report included the fact that EPA:

- had not established a program to verify that the registrants had actually removed toxic inerts from their products;

- had given potentially toxic inerts a high priority for testing in 1987, but as of 1991 had not started the testing; and

- knew little or nothing about the potential effects of the vast majority of identified inerts.

One example of delayed corrective actions is in the area of potentially toxic inert ingredients. The program planned to complete its review of the available data on these inerts in early 1993. This has been delayed until at least June 1995. The Acting Assistant Administrator stated that the main reason for the delay is a lack of funding. EPA requested funding for the inerts program in 1992 and 1993, but the budget suffered substantial cuts. Without adequate funds, the Acting Assistant Administrator stated the Agency expects to make slow progress.

CONCLUSION

For over 20 years EPA has been struggling with the tough scientific and public policy issues involved in regulating pesticides. For the last few years, my office has been reviewing the pesticide program. We have seen progress on some of our recommendations, and EPA has moved toward shortening the time it takes to reduce risks to humans and the environment from certain pesticides. Other issues discussed in our reports require longer term solutions. I am looking forward to working with the new Assistant Administrator, Lynn Goldman, to continue to address areas of concern in the pesticide program.

That concludes my prepared remarks. I will be happy to answer any questions you may have.

[The attached audit report by the Office of Inspector General entitled Special Review Process for Pesticides, dated July 22, 1993, is filed for the record in the office of the subcommittee.]

Mr. SYNAR. The Chair recognizes himself for 5 minutes.

First of all, Mr. Guerrero, let me thank you and the people at GAO for this investigation and the many investigations you have done over the years. We always appreciate what you do.

Let's be blunt about it. Will EPA meet the deadlines mandated by the 1988 FIFRA amendments?

Mr. GUERRERO. EPA will not. They will probably take until the year 2006 to complete reregistration.

Mr. SYNAR. How long was it supposed to originally take?

Mr. GUERRERO. It was envisioned in 1972 that this process would take no more than 3 years.

Mr. SYNAR. And I know that EPA's staff always thinks this is a cheap shot by this subcommittee, so let me remove all doubt that we do believe that there are very fine pesticide program staff down there, but the fact is that it is just not getting done.

In a nutshell, what is the problem?

Mr. GUERRERO. The problem seems to stem from several root causes. The first, insufficient resources to get the task done. The second, and we have documented this time and time again, has to do with EPA's lack of adequate management information systems to process the thousands and thousands of test results that come in to support reregistration.

The third is probably an overestimate on what EPA can reasonably accomplish given its resources and the time it had to do the job. Closely related is the fact that, because EPA was so optimistic, it failed to adequately plan to put into place a procedure for reducing pesticide risk by concentrating on the highest priority pesticides first.

Mr. SYNAR. Let's look at some of these examples from your report which you released in May. When Congress amended FIFRA in 1988, did EPA have a clear idea of what reregistration was?

Mr. GUERRERO. No. At that point it had not reregistered any pesticide.

Mr. SYNAR. So, for example, did EPA literally define reregistration?

Mr. GUERRERO. Yes. In fact, it wasn't until 1992 that EPA defined reregistration and the key elements.

Mr. SYNAR. How are they doing so far? How many have been completed?

Mr. GUERRERO. As I mentioned, EPA has reregistered about 1 percent of the pesticide products in commerce. That is about 250 products, and they have issued reregistration eligibility decisions affecting some 70 active ingredients.

Mr. SYNAR. Now, this may be new to some of our Members, so what is the difference between an RED, which is a reregistration eligibility document, and a product reregistration?

Mr. GUERRERO. The RED is a preliminary step. It is EPA's determination that the active ingredient, and actually EPA has classified those active ingredients into what they call chemical cases, but it is EPA's determination that those active ingredients pass muster. Then EPA has to go the second step, which is to look at the 20,000 products out there that contain those active ingredients and reregister each of those.

Mr. SYNAR. But issuing an RED doesn't mean that the product has been reregistered.

Mr. GUERRERO. That is correct.

Mr. SYNAR. What happens if a pesticide company disagrees with the RED recommendation?

Mr. GUERRERO. Ultimately, if the dispute can't be resolved between EPA and the registrant, EPA could seek to cancel that product and its uses.

Mr. SYNAR. But if a disagreement ensues, the reregistration could be even further delayed beyond the 2006 mark that you have already noted.

Mr. GUERRERO. That is correct.

Mr. SYNAR. All right. Now, you mentioned how the rejection rate for studies committed by pesticides companies has been very high. Why is that?

Mr. GUERRERO. Well, EPA has looked into that question itself and they have done a study, and I think that is an excellent question to pose to EPA.

Mr. SYNAR. We intend to do so.

Mr. GUERRERO. We do know that EPA had estimated the rejection rate at about 10 percent and that it is closer to 45 percent in some cases. To some extent, EPA is responsible for that because it has not gotten out to the registrants in time clear guidelines for conducting those tests.

Mr. SYNAR. So what does that do to the deadline 2006?

Mr. GUERRERO. It puts it in question.

Mr. SYNAR. Now, has EPA's schedule been adjusted to reflect those actual rejection rates?

Mr. GUERRERO. No, it has not. EPA continues to assume a 10 percent rejection rate on studies.

Mr. SYNAR. Is it correct to assume that the longest delays occur when EPA receives a study, doesn't review it until some time later, and then rejects the study, thus requiring it to be redone and resubmitted.

Isn't that really where all the delay is?

Mr. GUERRERO. That is one key area. Clearly, there are lots and lots of studies waiting to be reviewed. In fact, for list A pesticides, which are primarily food use pesticides, there are probably somewhere in the vicinity of 3,000 studies that have not yet been reviewed.

Mr. SYNAR. So there are 3,000 unreviewed studies presently?

Mr. GUERRERO. Somewhere in that ballpark, yes.

Mr. SYNAR. Is this a source of potential further delay?

Mr. GUERRERO. Absolutely. Because what happens is, if those studies are not reviewed as quickly as possible, EPA can be several years down the road and recognizing when it gets around to reviewing a key study, that it is either incomplete or raises additional questions requiring the applicant to go out and restudy those issues. Any new studies can take up to 4 years to complete.

Mr. SYNAR. So that 3,000 number is out of a total number of what?

Mr. GUERRERO. Well, they had——

Mr. TRAPANI. I believe that is out of about 9,000 total studies received.

Mr. SYNAR. OK.

Mr. GUERRERO. They have, Mr. Chairman, studies that were received before 1988 and studies received afterwards, and they have done a better job after FIFRA 1988. There were over 10,000 studies prior to that time that they needed to review.

Mr. SYNAR. You also stated in your testimony that there are going to be some delays because of data gaps. Weren't those list A pesticides we've been talking about explicitly the ones for which EPA had already issued reregistration standards?

Mr. GUERRERO. Yes. In fact, EPA provided assurance to the Congress when FIFRA was amended in 1988 that they could proceed with those list A pesticides. But they found out later that the reregistration standards they had issued were not adequate, the data that was submitted subsequently raised more questions and they required additional studies.

Mr. SYNAR. Mr. Mica for 5 minutes.

Mr. MICA. Thank you, Mr. Chairman. After only 10 months as a Member, I become more and more dismayed with EPA. Each day I have an opportunity to serve and I know that some of the responsibility for carrying out these mandates has—well, all the responsibility has been imposed by Congress and you have an oversight responsibility, and are trying your best to see how the system can be improved.

You both raise some interesting points. Mr. Martin, you raise three points about why EPA can't perform these tasks. One was insufficient resources, correct? What was the second one? The third was no plan. Is it management, insufficient resources, and no plan?

Mr. MARTIN. Well, those are all issues, Mr. Mica, that we have talked about in relation to this program.

Mr. MICA. Well, I guess the question here is the delays, both in responding to Congress, and then you have got industry out there hanging by a thread.

You have created nonproductivity in our economy. You have created a situation where we are unable to compete, say, in the marketplace, and you identified, at least as I caught it, it was management, insufficient resources, and no plan.

I am wondering what is the biggest factor here in the delays. Is it back to management or is it no—still no plan or insufficient resources?

Mr. MARTIN. I don't think there is any doubt, as we have studied the pesticides program over time, that they are overwhelmed with the amount of work that they have to do.

One of the things that we point out in our special review report, for example, is how, because of their resource constraints, every year they take a completely different look at what pesticides they ought to work on that year.

For example, in the special review process, because their workload is so high they are constantly reprioritizing based on the highest risk that they see, and they are never able to address all of the issues that they are presented with.

Mr. MICA. So they are often reinventing the wheel as far as their priorities?

Mr. MARTIN. Well, that is part of their regular practice, going back on an annual basis.

Mr. MICA. Too much on the platter.

Mr. MARTIN. Yes, that is true.

Mr. MICA. You have previously testified before us and we have discussed the management problems at EPA. Is there any improvement on the horizon in the areas that we are talking about today?

Mr. MARTIN. Well, in the areas that my testimony relates to, we have seen improvements, for sure.

Mr. MICA. In the last 10 months?

Mr. MARTIN. Well, in response to the audit reports that we issued that involve labeling and the special review process, we think that EPA is being responsive to the issues that we have raised.

Mr. MICA. Do you think that the Congress should come back and look at FIFRA and again make revisions there that would expedite the process?

Mr. MARTIN. Well, once again, I think as Mr. Guerrero said, there are a variety of legislative changes that can be made to address technical issues involving the agency. That has not been the focus of my testimony today but——

Mr. MICA. But, again, you have to look at the problem, and I look at it from a management standpoint or business standpoint. You either don't have the resources, the management, or a plan in effect, or the people who are imposing the mandates, and that is the people in Congress—there is probably too much on the platter.

There were some revisions made, as I understand, if we go back to 1988—the ability to impose user fees or processing fees. Is that working? Is that helping? Is that providing additional resources?

Mr. GUERRERO. Those fees certainly have helped, but they have proven to be insufficient and that is why EPA is coming back in to ask for additional fees.

Our point is, however, what they are asking for will also prove to be insufficient.

Mr. MICA. Let me ask another question. Are they conducting most of these studies in-house or are some of them being contracted out?

Mr. GUERRERO. The studies to support reregistration are required to be prepared by the registrants themselves, so they are done outside EPA. They come into EPA and EPA then has an obligation to review them.

Mr. MICA. But within EPA is all the review done within EPA or is any of that contracted out?

Mr. MARTIN. Ms. O'Lone might be able to help us.

Ms. O'LONE. I believe most of it is internal, but I am not sure exactly the division between their contractor work and their internal processes.

Mr. GUERRERO. The majority is done within EPA. There are some that are contracted.

Mr. MICA. Well, what I am trying to also ascertain is if there is some other way we can approach this to make the process go faster. If EPA can't handle it, maybe some of the review process could be contracted out and be done more efficiently.

Mr. GUERRERO. What we would recommend that EPA do is set priorities, concentrate on those pesticides that, either because of their high volume or health and the environmental risks, merit priority attention at EPA.

Mr. MICA. But Mr. Martin has testified today that they can't set priorities or they are constantly changing priorities. So maybe it is going to take an imposition from here.

Mr. GUERRERO. That is in fact what we recommended in our reregistration report, that in addition to EPA setting those priorities, that the Congress consider providing that direction to EPA by law.

Mr. MICA. OK, I have more questions. I will yield back.

Mr. SYNAR. Mrs. Thurman.

Mrs. THURMAN. Good morning, Mr. Martin. In your report, when you talk about the concerns with the process, tell me who the public is and how they have not been participating and how we can get them to participate.

Mr. MARTIN. That part of my testimony concerns EPA's special review process and what occurred was that in about the mid-1980's, EPA changed the process by which it dealt with pesticides through the special review process.

It basically eliminated certain specific criteria that they had and replaced it with more general judgmental type criteria. The problem was that since the mid-1980's, as EPA used the new process, it found that it was taking a very long time to bring that process to a conclusion.

It was taking on average about 5 years from when they began a special review process to when they concluded it. So their own management people decided to try yet a new strategy. The problem is that the new strategy is not officially recorded in any of EPA's public regulations about how they deal in a special review process. So there has been this informal process created involving negotiation between the registrant and EPA, and that is one of the main areas that, as we have reviewed this process, that we have suggested to them needs to be focused on. That is exactly the point of your question, how does the public, since this is now an informal process that is not on the books, how does the public become involved in an understanding of what is going on between EPA and the registrant.

This is an area that we believe the agency is responding to in response to our suggestions and is opening the process to some extent now to the public.

Mrs. THURMAN. You mentioned in a latter part of it how are they doing that now in these informal situations—I think you said they were informal—or was it efforts that would define the negotiation process and ensure continued public involvement?

Do you see that starting to happen and did you see that as a major problem before?

Ms. O'LONE. Yes, and we see it happening in a couple different ways. First, they are opening up files. There is a process called the public docket, and now some of those will be opened up.

Also, EPA is moving toward public hearings with regard to certain pesticides. I think EPA is still working on exactly how to involve the public. It is still an issue being worked on, but we are seeing progress. There is a work group. They are working at what went right and what went wrong in some of the past negotiations.

Mrs. THURMAN. What kind of information do you think they are trying to receive from the public? I mean——

Ms. O'Lone. Aside from comments, let me at least say one of the areas that was an issue when there was a pesticide parathion, there was an announcement that it was no longer going to be available for use after a December 31 deadline. That impacted a lot of farmers and user groups.

In that case, I think it was merely knowing when things are going to be done was an issue. December 31 looked better on paper than it did in some of the growing areas of the country, like California where they do have a winter crop.

Mrs. Thurman. Mr. Guerrero, in relation to that, and part of your testimony referred to it, I think, on the required studies.

Does this correlate with that, where they thought there were only going to be 10 percent of these that might be rejected and it then went up to 45 percent? Is this the kind of information that would help them?

Mr. Guerrero. If I could take a moment to address an earlier matter which I think explains why EPA has moved toward using a negotiated process for regulating high risk pesticides. I believe EPA has moved in this direction using voluntary discussions and negotiations, because it perceives that the regulatory procedures it has in place today for special review are too cumbersome. They tie up the agency in knots.

Certainly the lack of progress in this program is not attributable to the fact that EPA doesn't have dedicated staff and hasn't tried.

What it is more so attributed to is the fact that the process that is in place for making these decisions is fundamentally flawed, and EPA has tried to make the best use of that process, and when it has looked to the special review process, which is the process in place to answer these questions about high-risk pesticides and has seen that it has come up against a brick wall because it is too cumbersome, too burdensome, and too fraught with delays, it has tried this other negotiated approach, and as we have seen here today, that doesn't seem to be resolving these issues quickly either.

In recognition of this, the administration's proposal does call for an orderly phaseout and phase down of pesticides when EPA has information brought to its attention that those pesticides may be causing problems. Those certainly are the kinds of changes I think that the Congress needs to be thinking about seriously when it comes to reauthorizing this statute.

Mrs. Thurman. OK, thank you.

Mr. Synar. Mr. Guerrero, let's talk about food safety and the plan the administration has come up with. Is this plan viable?

In other words, will this program, which has taken over 20 years to get this far, complete the review of all the tolerances in the next 7 years?

Mr. Guerrero. Since the review of those tolerances is dependent upon progress in the reregistration program, it probably will not.

Mr. Synar. And what are the major obstacles?

Mr. Guerrero. The major obstacles were insufficient resources to do that job on time, inadequate management information systems, and a lack of a set of priorities and plan to address the highest risks first.

Mr. Synar. And the current funding and staffing are just not adequate?

Mr. GUERRERO. That is right.

Mr. SYNAR. The current program and current budgets project a $20 million shortfall. What happens if that $20 million is not funded?

Mr. GUERRERO. It may take longer.

Mr. SYNAR. Even beyond the 2006 date?

Mr. GUERRERO. That is correct.

Mr. SYNAR. Does EPA have tolerance reassessment guidelines in place which can do the job today?

Mr. GUERRERO. That is also another issue. EPA does not have all of its guidelines in place to allow it to set those tolerances.

Mr. SYNAR. Well, I think most of us support the fundamental notion of the proposal, which is to identify these high-risk pesticides and act quickly, but the question is, what is the ability of EPA to act quickly on high-risk pesticides?

Mr. GUERRERO. I believe they can. I believe a number of steps are needed first. I think they need to be very explicit about what the information data shows. They have information in hand that suggests that some of these pesticides present potentially greater problems than others.

They ought to be forthcoming with that and set priorities based on that information.

Second, they have production information. They can match that production information with the risk monitoring information they have. I believe that they could do that today if they wanted to, and that type of management of the program is absolutely necessary, because no matter how many resources they get to take on new initiatives, such as reviewing tolerances, it still is going to fall short when you look at the universe of pesticide products out there, that number of 20,000, and you look at the numbers of the studies that EPA needs to review, which numbers in the tens of thousands.

Mr. SYNAR. One of the things that can make this thing work is interagency cooperation between the three major food safety agencies. How well has that worked in the past?

Mr. GUERRERO. There have been problems. EPA, FDA, and USDA are the key agencies and they do need to work cooperatively to get the job done. We found in the past there have been problems. One example is USDA's food consumption survey where EPA was not sufficiently consulted and therefore the data developed wasn't of as great a benefit to EPA as it could have been.

Mr. SYNAR. Talk about data collection. Am I correct that one of the past horror stories which we revealed here is that you all asked them for a comprehensive list of canceled pesticide registrations, but EPA couldn't even provide you that?

Mr. GUERRERO. That is correct.

Mr. SYNAR. So the data collection problem still exists, doesn't it?

Mr. GUERRERO. It still exists, unfortunately.

Mr. SYNAR. Does the administration's proposal address the major problems identified that you have worked on over the years?

Mr. GUERRERO. We believe that there are a number of initiatives contained in that proposal that address some of these concerns. We talked today about reviewing—setting a uniform risk-based standard for resolving the differences between the key laws.

We talked about reviewing tolerances against that new health based risk standard. We talked about addressing some of the concerns EPA has with removing problem pesticides from the market by creating an orderly phaseout and phase-down process by regulation.

There are proposals to deal with some of the issues raised by the inspector general today where EPA can, in a more expedited manner, deal with the labeling and compliance with labeling requirements. And finally, there is sunset.

So there are a number of things and I could continue on. But fundamentally, regardless of whether the proposals are enacted into law or not and regardless of whether EPA gets these additional tools to do its job, it is critical that it continue to address the management issues, that it continue to look at what it can reasonably accomplish given the level of resources it has for the program, that it fix the information management problems it faces, and that it determine a reasonable approach for using the resources it does have to deal with the most risk reduction it can achieve with those resources.

Mr. SYNAR. Mr. Mica.

Mr. MICA. Mr. Martin, again, I am reminded of our earlier hearing on the management information systems and again today you have testified that basically that area is still out of control.

Is there any progress since we last met on what they are doing to correct the situation? As described, if I may recall, there was a third of a billion dollars spent in this area and basically it was a disaster. Since you last testified, can you tell us where we are?

Mr. MARTIN. I think the specific information today, Mr. Mica, came from GAO testimony about the management information system. I think Mr. Guerrero can address that.

Mr. GUERRERO. Yes. We reported that EPA certainly recognizes this as a problem. It made an investment.

Mr. MICA. I would hope so.

Mr. GUERRERO. And they have taken steps to correct it. In fact, we reported that they have invested more than $14 million worth of—in systems to increase the reliability of pesticide information, but they are still not there, and an example of that is——

Mr. MICA. Is there a plan to get there? Is the Administrator paying attention to this area, the new Administrator?

Mr. GUERRERO. I think the new administration needs to pay attention to this.

Mr. MICA. Is it possible to get a letter on the progress of that from you all? Can you look at that, tell us where we are, where we are going? It is only a third of a billion, I know that is not much money, but if you had—you weren't here.

Mr. Martin was here when we had that hearing. I damn near fell off the dais, pardon my French, when I heard the situation there. It doesn't sound like we have really targeted it in order to correct it. And one of the problems that was pointed out, the three problems I go back to are management, management information systems, and insufficient resources. That is in there too, and no plan. So that is all of it.

So I would like you all to get back to me on that and to the subcommittee if you could.

What was the original cost of the reregistering program estimated to be? Do you recall?

Mr. GUERRERO. I don't have that information.

Mr. MICA. Do you know, Mr. Martin.

Mr. MARTIN. No, I don't.

Mr. MICA. Anybody know?

Mr. TRAPANI. I believe the original estimate was $260 million.

Mr. MICA. What are we looking at a cost, final cost?

Mr. TRAPANI. Out to 2006, about $418 million, EPA's current estimates.

Mr. MICA. Originally some of these special reviews were to take 18 months average estimate. What have you found now? Like some of these reviews are totally out of whack.

Is there—say of what has been done today, what is the average time?

Mr. MARTIN. In the special review process, which is what we believe led the agency to recognize its own problem, the average was taking about 5 years. Some were taking 10 years to finish. That is what led them to this, first of all, not starting any since 1988, but developing this alternate negotiation process.

Mr. MICA. Another thing that I think you mentioned, Mr. Guerrero, was the question of imports and violating FIFRA. Did I hear something of that? I am a little concerned, wondering here now, we are registering all of these substances and pesticides.

What is happening as far as our ability to control the growing international marketplace? Are we imposing all these constraints on our manufacturers and folks and having—with NAFTA and international trade increasing, is this becoming a more important factor?

Mr. DONOHUE. The emphasis has to really shift to FDA to monitor the food being imported into the United States. It is very important.

For instance, in Mexico, they have almost a nonexistent system for monitoring pesticide residues, so, therefore——

Mr. MICA. So that all the work we have done to eliminate, for example, DDT and EDB, we have really no control over products coming in from Mexico?

Mr. DONOHUE. There are some international agreements called the PIC, prior informed consent.

Mr. MICA. But really if we get right down to it, we are not able to detect these substances coming in in those products?

Mr. DONOHUE. Yes, we have and we do test for them. DDT is tested heavily. Mexico does not allow DDT on any food crops. It is allowed in southern Mexico to take care of mosquitoes. It is a health concern in southern Mexico.

Mr. MICA. But you can assure me that this isn't a problem?

Mr. DONOHUE. I am not FDA. I couldn't assure you it isn't a problem.

Mr. SYNAR. The gentleman's time has expired.

Mrs. Thurman.

Mr. Martin, let's look at your report. You stated that EPA has not started any special review since 1988. That doesn't mean that EPA hasn't found a problem with any pesticides since 1988, does it?

Mr. MARTIN. Certainly not.

Mr. SYNAR. Now, according to the original legislations, EPA would have to start a special review which was previously known as a rebuttable presumption if the risk triggers were exceeded; is that correct?

Mr. MARTIN. That is correct.

Mr. SYNAR. Now, because of the regulations of 1985, exceeding that risk trigger may, not shall, force an EPA special review, right?

Mr. MARTIN. EPA did a couple things. One thing they did was to move to a more permissive and judgmental position on their part, but they also changed what you are referring to as triggers themselves, to make them more general and more judgmental and not as specific.

Mr. SYNAR. Now, did we direct them to do that or did they just do that on their own?

Mr. MARTIN. I don't know of anyone that directed them to do it.

Mr. SYNAR. So why did the program make exceeding the risk triggers an optional clause?

Mr. MARTIN. We understand their position was that the rigidity of the original system did not allow for them to consider enough different information, enough or unusual circumstances that involved particular pesticides.

Mr. SYNAR. It basically was too cumbersome and it made them make too many decisions, didn't it?

Mr. MARTIN. Well, it was too specific and triggered an automatic process that they had difficulty dealing with.

Mr. SYNAR. But the program never announced that the triggers, such as causing birth defects or injuring workers, were no longer a concern to them, right?

Mr. MARTIN. Well, I am not sure I would want to say that injuring workers is no longer a concern to the agency. I believe that there was a process that the agency went through, certainly in the mid-1980's, to change the system.

Mr. SYNAR. Those are still concerns but their program doesn't get to them any more quickly, correct?

Mr. MARTIN. Well, they are concerns. But specific triggers are not automatically applied the way they used to be.

Mr. SYNAR. So there are no specific guidelines, there are no really defined areas of adverse effects that will trigger this, correct?

Mr. MARTIN. That is true.

Mr. SYNAR. If there are no guidelines, how long will a special review take?

Mr. MARTIN. There are no timeframes.

Mr. SYNAR. So after receiving the information which exceeds the special review trigger, EPA can literally take forever?

Mr. MARTIN. Well, I would assume forever is the outer-most edge.

Mr. SYNAR. I don't think EPA assumes that. If something does get placed in special review, Mr. Martin, how long can it take to finish?

Mr. MARTIN. There are no timeframes.

Mr. SYNAR. All right, and has it been suggested that EPA set down some guidelines for these milestones and decisions that ought to be developed?

Mr. MARTIN. That has been a repeated suggestion over many years by both GAO, ourselves, and I understand even this subcommittee.

Mr. SYNAR. Yes. We have made repeated efforts. I think between the three of us, they would listen to somebody, don't you think?

Mr. MARTIN. Well——

Mr. SYNAR. Are you satisfied with the program's response to your recommendations over the years?

Mr. MARTIN. In the areas that we talked about today, Mr. Chairman, they are making an effort to deal with the labeling issue, the special review issues we have raised, not as much with the inert ingredients issue we talked about earlier.

Mr. SYNAR. Let's talk about that labeling. You issued your report last September. As a result of that report, what is your confidence level that product labels are accurate and give reliable information to the users of pesticides?

Mr. MARTIN. We found substantial problems with the sample that we looked at. Of the products we were able to examine, we found up to 40 percent had serious labeling problems.

Mr. SYNAR. So for almost 40 percent of the pesticides examined, you didn't have a very good confidence level on the labels, correct?

Mr. MARTIN. That is right.

Mr. SYNAR. Mr. Guerrero, given GAO's investigation, does this surprise you?

Mr. GUERRERO. No, it doesn't.

Mr. SYNAR. There is not much confidence here in EPA today, is there?

Let me mention to both of you a memorandum which has come to the attention of this subcommittee. In July 1992 a memorandum from Doug Campt, Director of Pesticide Programs to his division directors, it states, "OPP employees cannot definitively determine the scope of registration of a product from its labeling or any other means. In addition, OPP employees may even have difficulty in physically locating the label."

It goes on to say in this memorandum that in some cases, OPP's staff are not sure if all the uses listed on the label in the files reflect all the uses which have been approved for that product over the years.

I guess the question here to you, Mr. Martin, doesn't that affect EPA's ability to conduct risk assessments or conduct enforcement of label restrictions?

Mr. MARTIN. I am not familiar with the memorandum you read, but there is no question that they have problems in the areas you are talking about.

Mr. SYNAR. But missing and wrong information can be life threatening, can it not?

Mr. MARTIN. It can be.

Mr. GUERRERO. I would add, Mr. Chairman, the labels are the end product of this whole process, that EPA is going through this reregistration process to ultimately put on the product label the restrictions and use conditions, and if those are incomplete or inaccurate or out of date, then the process has failed.

Mr. SYNAR. Mr. Martin, you note that EPA has taken some steps to address most of the recommendations in the report; is that correct?

Mr. MARTIN. Yes, that is right.

Mr. SYNAR. One last request, Mr. Martin, before we let you go this morning. Later we are going to ask EPA about the pesticide Benlate which appears to have caused widespread damage, over $500 million in damages to crops in Florida and other places.

Now, given what we have learned so far, there are some very serious questions raised about whether DuPont, which makes the pesticide, has been forthcoming with EPA, and whether they complied with information disclosure requirements under the pesticide law. We are going to ask EPA about that subject in a few minutes.

At the same time, there has been questions raised about EPA's handling of the information they were given, some personnel assignments and transfers to regional offices, and their overall responsiveness to the incidents in Florida.

Would you please have your office look into the matter and report back to this subcommittee as to whether the matter has been dealt with according to the required procedures regarding handling the information and personnel assignments within EPA?

Mr. MARTIN. I am not familiar with the issue, Mr. Chairman. We work with your staff on a regular basis and we will certainly take a look at the issue that you are laying out, to determine what our proper role can be and work with you in any way that we can.

Mr. SYNAR. Thank you, Mr. Martin.

Mr. Mica, any questions?

Mr. MICA. Gentlemen, in a general sense, EPA is responsible for ensuring that when used properly, a pesticide does not present an unreasonable health or environmental risk. However, isn't there always some risk in using pesticides?

Mr. MARTIN. I think every pesticide you pick up has all kinds of cautionary notes on it about the risk of using it improperly.

Mr. MICA. Even all those that are properly labeled and have gone through this entire process?

Mr. MARTIN. The proper labels would be telling you what the risks are.

Mr. MICA. You have been involved in this process. How would one define "risks"?

Mr. GUERRERO. The kinds of risks that EPA regulates are for birth defects, cancer, environmental harm.

Mr. TRAPANI. Ecological effects, mutagenicity; that basically covers it.

Mr. MICA. And we really haven't been able to prioritize risks within the agency, from what I have been able to see, have we?

Mr. MARTIN. The agency has worked very hard, I know, over the last several years exactly to do what we are talking about, and to make—and to raise the level of public awareness, even public debate, over the issues of risk generated the agency deals with and how our funding should be more risk related.

Mr. MICA. Well, when we get through with all this and we spend all these billions, and we drag these companies through all of the hoops and over the hurdles that we have created, can we ever determine that a product is really safe?

Mr. GUERRERO. I think it is a matter of relative risk. All these products by definition are products designed to kill living organisms. So there is always some risk associated within the questions whether EPA has dealt with the worst actors first.

Mr. MICA. But you can OD on just about any substance. A lot of us do it daily with a knife and fork, just consuming, and we all know the risks involved in overeating. And if you take a bottle of aspirin and it has—I guess one of its compounds is benzene—you can go by the wayside.

Mr. GUERRERO. There are certainly risks that we face daily in addition to pesticide risks. Pesticide risks are not the only ones. But the other thing that speaks for itself here, when you look at what EPA has done in reregistering pesticides, fully 50 percent of those that have been reregistered to date are not the list "A" food-use pesticides. There are list "C," "D"; so that is the issue.

Mr. MICA. The other thing, too, as we are going through this whole process, we have been through a registration process, we are in a reregistration process, and the administration is coming out with a sunset of the registration process. We are going to be going through this again.

Do you think we will finish what we start before we have to do it over again?

Mr. GUERRERO. Well, I think this is precisely why the chairman's opening remarks about reinventing this program were germane. Because the process that we face today is a process that is never-ending, has produced few results, and has been incapable of resolving the public's concerns.

Mr. MICA. Have you all favored the sunset provisions recommended by the administration?

Mr. MARTIN. I think Mr. Guerrero is saying that whether you have a sunset provision or not, the issues are almost overwhelming. And unless there is a way to somehow reduce the workload more inline with what the greatest risks are that we face, it is almost an impossible task with the tens of thousands of actions that have to be taken; it is almost an impossible task for anyone to complete.

Mr. MICA. Well, just, I guess, to finalize, or sum up here: We don't have management in place, we don't have the resources, we don't have a plan. The chairman has outlined here a number of times that you have been asked to come back with various timetables and requests of the committee and no one is responding. This also seems out of control. So it would be my hope that you—we can make some sense out of this, that we have got industry left in the lurch, people, as far as their health safety, left in the lurch.

And I don't see us making a whole lot of progress. I hope also some of the information that I requested today, especially on the management systems, can be provided to the committees. Maybe we can make a chip and a dent and start looking toward some reasonable and successful and productive approaches here.

Mr. GUERRERO. We are on the record as having made specific recommendations on management information and we are waiting for the agency's response, and when we have the response, we will certainly share it with you.

Mr. MICA. Thank you.

Thank you, Mr. Chairman.

Mr. SYNAR. Thank you, Mr. Mica.

Mr. Martin, Mr. Guerrero, we really appreciate you and those accompanying you being here this morning. We will come back again to these issues, so keep posted.

Our second and final panel this morning will be the newly sworn Hon. Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances; and the Honorable Richard Rominger, Deputy Secretary, U.S. Department of Agriculture.

As you saw from the previous panels, we swear in all our witnesses.

Do any of you have any objections to being sworn?

[Witness sworn.]

Mr. SYNAR. This is a new day. Not only do we have a new Assistant Administrator, Dr. Goldman, but we also have for the first time all the agencies of jurisdiction on pesticides under this subcommittee jurisdiction, so that we now have a full table.

Dr. Goldman, the policy is to allow you to submit your prepared testimony for the record, and we ask you to summarize it this morning.

STATEMENT OF LYNN GOLDMAN, ASSISTANT ADMINISTRATOR, PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY MICHAEL R. TAYLOR, DEPUTY COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GOLDMAN. I will do that.

Good morning, Chairman Synar, members of the subcommittee. I am Lynn Goldman, Assistant Administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances. As a new appointee, I am happy to have the opportunity to address this subcommittee today to discuss the pesticide activities I will be overseeing in my new position.

Having worked all my professional life in public health, I care about pesticide issues because I have seen what impact exposure to such products can have on health and the environment. I realize that my new position at the EPA involves enormous responsibility, and we have just heard about some of the challenges. I take this responsibility seriously and look forward to working closely with you to do the best job possible.

Today, I will give an outline of the legislative reforms that we are seeking and why these reforms are so important. I will also discuss the new initiatives that the administration has announced in the areas of reducing risks of pesticides to children, and reducing the use of pesticides in this country.

Finally, I will briefly describe some of the difficult issues that I will be dealing with in the near future.

Vice President Gore has asked government to focus on its customers. I see that under the current system of regulating pesticides, we fail to do that. The general public lacks confidence that public health and the environment are adequately protected. The pesticide industry experiences a slow and unpredictable regulatory system, and farmers don't believe they can count on products being available for them when they need them.

We do have a professional and committed staff at the EPA who can provide these office services, and I am impressed that they have developed clear management plans. But without legislative reforms and adequate resource, the program cannot serve its customers well.

In developing legislation proposals, we are committed to the principles that Administrator Carol Browner has articulated in using good science and pollution prevention strategies in environmental regulation. We believe that only fundamental pesticide reform can meet these goals.

I want to stress that the proposals developed by the administration reflect months of discussion by the three involved agencies, and in the light of that, I did invite Michael Taylor from the FDA to join us at the table so that he could participate in our later discussions.

Some of our general features are a strong health-based standard on pesticide residues in food and review of all tolerances to ensure they meet this standard; a number of FIFRA reforms to streamline our activities and allow us to act promptly when real concerns arise about pesticides; streamlining of label change procedures; a registration sunset every 15 years; movement toward lower-risk pest control measures and increased use of integrated pest management techniques; protection of minor-use registrations; improved enforcement authorities, and increased registration fees.

And I would like to emphasize with respect to the first proposal, that I do believe that it is feasible for us to review the pesticide tolerances because we propose to shift the burden to the registrants to prove to the agency that the residues are safe. We are working with Congress to draft legislative language reflecting our provisions. We realize that not everyone will like all of the provisions of our package, but we do feel that most of the customers of our three agencies will be very happy to have these changes.

We are looking forward to working with you and other Members of Congress on these reforms.

The other things that are happening, just to summarize briefly; first, this summer the National Academy of Sciences released a report, Pesticides in the Diets of Infants and Children, and we do have a very active working relationship with FDA and USDA and work groups to address the findings of that report. As a pediatrician, I am very enthusiastic about carrying out these initiatives.

Also, the administration announced last June, for the first time ever, the goal of reducing the use of pesticides and moving toward sustainable agriculture. The EPA and the USDA will develop within a year a plan with commodity-specific goals and timelines for reducing pesticide use. In the planning process, we will involve farmers, environmentalists, and other interested parties.

Now, I would like to turn to a couple of the problem areas that I need to deal with. First is the Delaney clause. As you are well aware, in July 1992, the Ninth Circuit Court of Appeals rejected the EPA's de minimis interpretation of Delaney. The court said that while more than one scientific authority had criticized the Delaney clause, that revising the existing statutory scheme is neither the court's function, nor the function of the EPA. If there is to be a change, it is for Congress to direct.

To date, the EPA has taken several actions, including publishing a list of the over 80 tolerances that might be affected by the court's decision, revoking or denying 21 emergency exemptions under section 18, and issuing revocation notices for seven tolerances for the four chemicals named in the court's decision. We expect to move very soon on requests for hearings and stays on the latter revocations.

Further action is needed. EPA has proposed to revoke the tolerances for the use of two more pesticides, dicofol on dried tea, and DDVP on packaged and bagged nonperishable foods. This week, we did reissue the final revocation notice for DDVP, and I will issue the final notice for dicofol as soon as it is ready.

The EPA will also shortly be issuing a policy statement announcing that we will immediately discontinue processing applications for experimental use permits, product registrations, petitions for tolerances for chemicals that are potentially affected by the Delaney clause.

It makes little sense for the agency to expend our limited resources to process applications for the same sorts of uses for which we were in the process of revoking. We can also quickly begin to revoke a number of other section 409 tolerances within a matter of months.

There are a number of remaining legal and policy issues, but I think the court made it quite clear that we should not take extraordinary measures to circumvent Delaney, as the EPA tried to do in the past. Once these policy decisions are set, we will announce how EPA will deal with the remaining pesticides affected by the court's decision, and also the issues that were raised in the National Food Processors Association petition.

Hopefully, Congress will act quickly with legislation that replaces Delaney with real pesticide safety reform, but for our part, the court has ruled and the clear requirements of the law will be carried out.

Another ongoing challenge is the reregistration program. I come to the agency at a time when this program, initiated in 1988, is finally beginning to produce its intended end products, namely, reregistration decisions. And I believe there is, at this time, a strong data management system in place to support this program.

As of today, the agency has issued 47 REDs, covering 72 active ingredients and 2,670 products. Of those REDs, 16 were produced in the last 4 months.

To date, 250 individual products have been reregistered and around 900 products covered by REDs have been canceled or in the process of being suspended for failure to complete phase five reregistration requirements. Because the startup work of the reregistration program has finally been completed, we can expect that the pace of reregistration will continue to be much more rapid than in previous years.

EPA has almost completed calling in the data needed on the active ingredients to be reregistered, and we expect to receive between 20,000 and 30,000 studies on active ingredients over the course of this program. We do project that by 1997, we will issue

REDs on 86 percent of the list "A" chemicals. These are the highest priority, high volume food-use pesticides.

To conclude, significant problems do remain. We are aware that there is a large backlog of over 14,000 studies to be reviewed and we do agree with the GAO's estimation for completion date of 2006. This is a complex and massive program that has an enormous workload, and EPA is going to have to continue to make every effort it can to manage it responsibly in order to meet our statutory responsibilities. I think we also need the proposed increase in registration fees to speed the process.

One final point to make on reregistration; the experience of FIFRA, 1988, teaches us never to wait for 30 or 40 years to review pesticides on the market. Rather, such reviews should be ongoing and predictable. That is why the administration's proposal includes a mandatory sunset provision that will require every pesticide product registration to expire periodically, unless the products are shown to meet our constantly improving health and safety standards.

In an era of shrinking budgets, all government is being called on to reinvent itself to carry out our mission. EPA believes this is possible in the regulation of pesticides and has laid out nine blueprints for accomplishing this in its legislative proposal package. We hope Congress will consider these proposals carefully and pass legislation later this year.

I look forward to working with you to meet these challenges and I will be pleased to answer any questions that you may have.

Mr. SYNAR. Thank you, Dr. Goldman.

[The prepared statement of Dr. Goldman follows:]

STATEMENT OF
DR. LYNN R. GOLDMAN
ASSISTANT ADMINISTRATOR
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE
SUBCOMMITTEE ON ENVIRONMENT, ENERGY, AND NATURAL RESOURCES
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

OCTOBER 29, 1993

I. INTRODUCTION

Good morning. I am Lynn Goldman, Assistant Administrator for EPA's Office of Prevention, Pesticides and Toxic Substances. As a new appointee, I am happy to have the opportunity to address this committee today, to discuss the pesticide activities that I will be overseeing in my new position. Having worked all my professional life in public health, I care about pesticide issues because I have seen what impact exposure to such products can have on health and the environment.

EPA has an enormous responsibility with regard to pesticides. Recognizing that pesticides are biologically active chemicals and can have substantial risks associated with their use, EPA must above all assure that these products are being used safely. Further, it is incumbent upon the Agency to find ways to reduce the overall risks associated with the use of pesticides. At the same time, these chemicals have become basic tools in America's abundantly productive agricultural industry, and EPA in partnership with the U.S. Department of Agriculture has a responsibility to provide American farmers access to the tools and methods they need to produce the food and fiber consumers depend on.

Today I plan to outline the package of legislative reforms that we are seeking in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), and why these reforms are so important. I will then discuss two new initiatives that this Administration has announced -- a group of actions the Agency is taking in response to the National Academy of Sciences (NAS) study on pesticides and children, and a pledge by this Administration to reduce the use of pesticides in this country. Finally, I will briefly describe some of the difficult issues that I will be dealing with in the near future and why I believe that fundamental pesticide reform is needed at this time.

II. WHY IT WOULD BE HELPFUL TO HAVE LEGISLATIVE REFORMS

Vice President Gore has asked government to focus on its customers; I see that, under the current system of regulating pesticides, all of the Agency's clients are underserved. The general public is concerned that its health and the environment may not be adequately protected. The pesticide industry feels that the regulatory system takes too much time and is unpredictable. And farmers are anxious because they feel they can't count on products being available for them when they need them.

EPA already has a very ambitious pesticide program in operation, and its talented and committed staff are working here within the limitations of the Agency's resources and the statutory authorities given them. There are administrative improvements that are underway that I will support, but I believe that the true solution to the shortcomings of the current pesticide program lies in new legislation.

Congress is now in a position to change the laws to give EPA the ability to run a more effective and credible pesticide regulatory program. In testimony delivered in September, Administrator Browner, USDA Deputy Secretary Rominger, and FDA Commissioner Kessler explained in detail the pesticide and food safety legislative reforms that the Administration supports including changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The Administration's reform package has many features that will improve service for the general public, the regulated community, and farmers.

For the general public, who is concerned about food and environmental safety, we would establish a protective, health-based standard for tolerances and assure that pesticides are fully evaluated against that standard and that regulatory decisions are made in a timely fashion. To accomplish this, we propose to do the following:

1) establish a strong, health-based standard in FFDCA that would apply to all pesticide residues in food, that would provide greater assurance of protection for the health of children, and establish a process for reviewing all existing tolerances to ensure that they meet this standard;

2) require that EPA review all existing tolerances and ensure that they meet the new standard of a reasonable certainty of no harm, within seven years of enactment;

3) streamline the decision-making process. To do this we would:

   - make cancellation a rule-making process rather than formal, trial-type proceedings;
   - decouple the suspension and cancellation processes so that suspensions can be carried out faster;
   - simplify the process of making label changes so that relatively small changes in the use of a product or the information provided to the user could be easily achieved;
   - give EPA the authority to conduct rulemaking to "phase out" or "phase down" use of risky pesticides, through production caps or by eliminating certain uses;
   - establish a registration "sunset," under which pesticide registrations and tolerances would be renewed every 15 years to ensure that they conform with then-current health standards;

4) reduce overall pesticide risk by promoting the development of reduced-risk pesticides, and the increased use of Integrated Pest Management (IPM) techniques;

5) improve EPA's enforcement authorities, including enhanced inspection, record keeping and lab audit authorities, "whistle blower" and citizen suit provisions, and significant increases in penalties for FIFRA violations;

6) give EPA the ability to prohibit the export of any pesticide to a country that does not want to receive shipments under the international system of "Prior Informed Consent" (PIC): any pesticide not permitted in the U.S. due to human health concerns; and any food use pesticide that lacks a U.S. tolerance and/or analytical method capable of detecting residues in food;

7) provide increases in fees on registrants to provide added resources to allow EPA to fulfill the complex requirements of the reregistration process, and make sound regulatory decisions in a timely manner; and

8) in keeping with the National Performance Review, explore the potential for using market mechanisms in pesticide regulation.

To meet the needs of pesticide registrants, we propose to do the following:

1) eliminate the application of the Delaney clause to pesticide residues in food, replacing it with a science-based, negligible risk health standard;

2) establish clear priorities in our registration program, favoring the development of products with reduced risk;

3) establish a uniform national label compliance date, giving ample advance notice when label or other changes are required. This should be much less disruptive to the registrant's production process than the current system.

Finally, to meet the needs of farmers to have access to safe and effective pest management controls, our reforms would do the following:

1) expand technical assistance to farmers in the area of biologically-based integrated pest management and sustainable agriculture to reduce their dependence on toxic and persistent chemicals;

2) accelerate the registration of new, reduced risk pesticides, including biologically-based pesticides;

3) establish a transition period as we move to the new health-based standard for tolerances. For example, we would allow time-limited tolerances for pesticides that do not meet the health standard, but whose abrupt cancellation would cause significant disruption of domestic agricultural production; and

4) through a number of provisions, support Administration efforts to promote pesticide use reduction, development of reduced risk pesticides, IPM, registration of pesticides for minor uses, and the acceleration of the reregistration program under FIFRA '88.

These reforms would place an emphasis on using good science in establishing public policy and opening up the regulatory process for participation by all interested parties. And this package would do much to allow the Agency to focus on pollution prevention -- the best and most cost-effective approach to solving environmental problems.

There will be those of our customers who will not like certain provisions of this package because of their own special concerns. But I believe that, if the Congress adopts this legislative package, the majority of the customers of EPA's pesticide programs will feel that government has served them well.

III. NEW INITIATIVES

NAS Issues

Many of the positive changes that are coming to EPA's pesticide program were motivated by the release, this summer, of the National Academy of Sciences (NAS) report, "Pesticides in the Diets of Infants and Children." The NAS found that while the U.S. has one of the safest and most abundant food supplies in the world, our pesticide regulatory program should be modified to provide added protection for children.

As a pediatrician, I have a particular interest in the findings of the Academy's report. Much of my professional life has been focused on children's health issues -- while directing environmental programs in the State of California. EPA has a duty to protect all segments of society, including children. I am enthusiastic about carrying out the initiatives that the Agency has launched in response to the specific recommendations of this report.

EPA, USDA, and FDA presented in some detail the Administration's initiatives in Congressional hearings last month. Today I will briefly summarize the NAS findings and EPA's response.

One of the most significant findings of the NAS report was that infants and children, in their intake of pesticides in food and their potential sensitivity to toxic effects of pesticides, are not just small adults. Infants and children eat more per unit of body weight, and they eat different foods than do adults. Due to differences in metabolism and the stage of development of organs and other systems, infants and children may be more sensitive to pesticide toxicity than adults. As a result, their exposure and response to pesticides may differ substantially from adults.

The report made a variety of recommendations concerning how EPA evaluates pesticide toxicity, residue levels, and food consumption, and how this information is used in risk assessments. The Academy's recommendations, taken as a whole, present a great challenge in terms of higher standards for the quality, quantity, sensitivity, and scope of the data the Agency uses in evaluating risks from pesticides. This is a formidable challenge, but one we are prepared to meet.

EPA has made a good start at responding to the NAS recommendations. To begin, EPA has enlisted the support of USDA and FDA, who will be essential to bringing about the necessary changes. The Agency has also assembled a highly qualified team of experts from the three agencies, including experts from other branches of the Department of Health and Human Services, the Department of Commerce, the U.S. Census Bureau, and state regulatory agencies into six workgroups to address the issues raised in the NAS report. Primary attention is being given to ways to improve our data collection on food consumption for children and on related residue data.

We expect to achieve tangible results within the coming year, and are close to implementing some of the recommendations of the report.

For example, EPA is close to issuing guidelines for new types of toxicity testing that were recommended in the NAS report, including immunotoxicity and visual system testing. Also, the Agency will soon propose to make neurotoxicity testing -- another endpoint that NAS has said deserves greater attention -- a standard requirement for all food-use pesticides. These new testing guidelines, and the proposal regarding neurotoxicity testing, will be presented to the Agency's Scientific Advisory Panel (SAP) by early next year, and finalized following SAP review.

The report also recommends a number of program changes which will take considerable time and effort to implement. One important recommendation is that a national pesticide residue monitoring database be established, to improve the data used in estimating dietary exposure. Such a database would be valuable, and EPA, FDA, and USDA are currently working together on this project. Nevertheless, it is clear that a useful database collecting many types of unlike data will require an extensive investment in time and resources to establish. I will work with the USDA and FDA to identify how to improve our data in the short-term and develop a national residue database in the longer-term.

Use Reduction

EPA Administrator Carol Browner emphasizes pollution prevention in addressing pesticide and other risks regulated by EPA.

In June, the Administration issued a statement announcing its commitment to reducing pesticide use and promoting sustainable agriculture. Administrator Browner, USDA Deputy Secretary Rominger, and FDA Commissioner Kessler, announced a new goal of reducing the use of pesticides in this country through a variety of new and ongoing government programs. For the first time ever, the federal government has committed to real reductions in pesticide use.

Many environmental groups have asked the Administration to set numerical goals for pesticide use reduction. As announced in June of this year, promoting reduction of use of pesticides that raise risk concerns is a major goal of this Administration. As part of the Administration's regulatory reform proposal presented in September, EPA and USDA announced the beginning of a one-year process to develop specific use reduction goals for various segments of production agriculture to be achieved by the year 2000. We realize that establishing some per centage reduction target for the volume of pesticides used should be viewed as a means to achieve real risk reduction, and not as an end in itself. We will need to ensure that trade-offs made in the effort to reduce both agricultural and non-agricultural pesticide use actually result in reduced risk. In developing the use reduction goals and associated implementation plans we will include farmers, environmental groups, and other interested parties.

In addition, the EPA and USDA will promote sustainable agricultural and IPM practices. We are setting a goal of developing and implementing IPM programs for 75% of the total crop acreage in the U.S. in the next 7 years.

Our use reduction efforts will not be restricted to agriculture. One of a number of promising EPA activities is the "IPM in Schools" project, which reduces the use of pesticides in schools by promoting the use of integrated pest management techniques. Funds permitting, EPA hopes in the coming year to publish a guide to the implementation of IPM techniques for schools.

IV. DIFFICULT ISSUES EPA WILL HAVE TO DEAL WITH IN THE NEAR FUTURE

On the whole, I think that EPA's pesticide programs are headed in a positive direction. However, in addition to exciting new initiatives, EPA has some continuing pesticide issues that will be very difficult to deal with. First on the "tough issues" list is the Delaney clause.

Delaney Clause

The conflict which the Delaney clause has injected into pesticide regulation is well known to anyone working with these issues. This conflict was brought to a head by the decision, in July, 1992, by the U.S. Ninth Circuit Court of Appeals regarding EPA's interpretation of the Delaney clause. As you know, when the Agency tried to implement a de minimis policy to apply to pesticide residues in processed food which pose a trivial risk, the court rejected our interpretation, telling us to apply the Delaney clause literally.

Noting that more than one scientific authority has criticized the statutory scheme established by the Delaney clause, the court said, "Revising the existing statutory scheme, however, is neither [the court's] function nor the function of the EPA...If there is to be a change, it is for Congress to direct." EPA has already taken steps to carry out the court's decision, and I intend to speed up the pace of EPA's implementation of the court's interpretation of the Delaney clause.

In response to the court's decision, EPA has taken several actions, beginning with publication of a notice in the Federal Register on February 5th of this year, which listed 32 pesticides representing over 80 different chemical/crop combinations that might be affected by the court's decision. In addition, EPA, USDA, and FDA jointly issued a statement of policy on the way in which EPA will review and approve requests for emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act in light of the U.S. Ninth Circuit Court's decision. Acting according to this policy, in April of this year EPA revoked 5 previously-granted emergency exemptions and denied another 16 pending applications. Although EPA concluded that these emergency exemptions were genuinely needed and posed no unreasonable risks to public health, the Agency thought that it had little choice but to follow the court's interpretation of the Delaney clause.

On July 14th, EPA issued a revocation notice which responds to the U.S. Ninth Circuit Court's mandate by revoking seven tolerances for the four chemicals named in the court's decision. The effective date of these revocations was delayed automatically by requests for administrative hearings and stays. We expect to rule very soon on these requests.

While I believe these earlier steps were correct, there are a number of other actions that can and will be taken promptly. EPA has already proposed to revoke the tolerances for the use of two more pesticides, "dicofol" on dried tea and "DDVP" on packaged and bagged nonperishable foods. Both of these pesticides were subjects in the original petition which prompted the Delaney litigation, but were not addressed in the U.S. Ninth Circuit Court's decision. This week, I signed the final revocation notice for DDVP, and I have directed my staff to issue the final notice with respect to dicofol as soon as possible.

The EPA staff are also writing, and we will shortly be issuing, a policy statement announcing that we will immediately discontinue processing applications for Experimental Use Permits, product registrations, and petitions for tolerances, for chemicals that are potentially affected by the Delaney clause. It makes little sense to expend Agency resources to process applications for the same sorts of uses which we are in the process of revoking.

Finally, the clear, legal interpretation of the U.S. Ninth Circuit Court's decision plainly applies to a number of other chemicals and their tolerances. Although there are a number of legal and policy issues which EPA has not yet settled, I have decided that we can quickly begin to make some policy choices and initiate actions on a number of existing tolerances. Accordingly, I expect that additional notices to revoke section 409 tolerances will be proposed within a matter of months.

I will be dealing with the outstanding legal and policy issues early on. EPA's experience with its unsuccessful de minimis interpretation of the Delaney clause, however, makes me quite reluctant to attempt to address the inconsistencies in the statute through the process of statutory interpretation or major changes in EPA's past administrative practice, absent strong public health reasons for a departure. Thus, once these policy decisions are set, we will announce how EPA will deal with the remaining pesticides affected by the court's decision and to the issues raised in the National Food Processors Association petition. Our plan will establish priorities and schedules over the next year for revoking food additive regulations and raw food tolerances, as well as possibly canceling registrations.

Hopefully, the Congress will act quickly to avoid potential dislocations to production agriculture. But for our part, the court has ruled and the clear requirements of its ruling will be carried out.

Reregistration

Another ongoing challenge that I will have the opportunity to work with is the reregistration program. I come to the Agency at a time when this program, initiated in 1988, is finally beginning to produce its intended end-products, namely, reregistration decisions.

In June, the Acting Assistant Administrator for OPPTS, Victor Kimm, testified before a subcommittee of the House Committee on Agriculture regarding the registration and reregistration programs. In his testimony, he reported that the Agency had issued 31 Reregistration Eligibility Decisions (REDs); 47 active ingredients, involving about 2250 individual products were covered by these 31 REDs. I can now report that, as of today, just 4 months later, 16 more REDs have been completed for a current total of 47 Reregistration Eligibility Decisions covering 72 active ingredients and 2670 products. To date, about 250 individual products have been reregistered, and around 900 products covered by REDs have been canceled or are in the process of being suspended for failure to complete Phase Five reregistration requirements. *(See Attachment 1)*

As Mr. Kimm also testified, there are many reasons to anticipate that the pace of reregistration will continue to be much more rapid than in previous years. Largely, this is because much of what one might call the "start-up" work of the reregistration program has been completed.

EPA has almost completed calling in the data needed on the active ingredients to be reregistered; over 300 Data Call-In notices (DCIs) have been issued. We expect to receive 20,000 - 30,000 studies on active ingredients over the course of the reregistration program. EPA has also reviewed a substantial portion of the in-house studies, particularly those which are the most critical.

EPA has also made important management improvements to the reregistration process, particularly with respect to study rejection rates and waiver and protocol decisions. These changes should improve the speed of decision-making in the future.

We have ambitious goals for RED production over the next few years, and we project that by 1997, we will issue REDs on 86% of the List A chemicals, which include most of the high-volume food-use pesticides. *(See Attachment 2)*

However, there are also significant problems facing the reregistration program. For example, there is a large backlog of over 14,000 studies to be reviewed. As the General Accounting Office announced in the title of the report they issued in May, "Pesticide Reregistration May Not Be Completed Until 2006" (GAO/RCED-93-94). As you know, EPA first reported to Congress in the fall of 1991 that the statutory deadline of 1997 was unattainable with existing levels of resources.

We agree with GAO's estimate, and we believe that GAO's report fairly portrays the reregistration program, including its complexity and massive workload and the efforts EPA is making to meet its statutory responsibilities. Unless Congress supports additional resources for this program through appropriated funding or increases in reregistration fees, which can be found in our legislative reform package, all I can offer is that I will provide continuous oversight of the reregistration program in order to do the best that we can with the resources we have.

In this discussion of the reregistration program, I should also stress that it is not by RED production alone that the progress of the reregistration program should be judged. An unreregistered pesticide does not mean an untested pesticide, nor does it mean that we have not taken action to minimize its risks. The purpose of reregistration is to assure that older chemicals are used safely. Therefore, throughout the reregistration process, EPA has focused on taking action to eliminate unacceptable risks as they have been identified. As indicated in GAO's report, EPA has made an effort at every point in the reregistration process to achieve real risk reduction as information becomes available.

Not only have all REDs contained risk reduction requirements, but EPA has taken interim risk reduction measures affecting hundreds of pesticides, and has removed many uses or entire pesticides from the market based on new evidence of health and environmental risks.

This raises another set of questions that were the subject of a recent Office of Inspector General Audit Report on the Agency's pesticide Special Review process. In recent years, because of concerns about the length of time involved in Special Review deliberations, EPA has turned more to using alternatives to this formal process. One approach that has proven effective at delivering interim risk reduction is negotiation with the pesticide registrants.

There are clear and significant advantages in the speed with which negotiations can yield risk reduction actions, and I intend to maintain the program's emphasis on such methods. But as someone who was until very recently on the outside looking in, I am sensitive to complaints that EPA's negotiations provide for insufficient public involvement in Agency deliberations. I will try to find ways to make the process of making important reregistration decisions more transparent and to put out decisions in ways that allow the public to see how we reached them.

One final point to make on reregistration: the experience of FIFRA '88 teaches us never to wait for 30 or 40 years to review pesticides on the market. Rather, such review should be ongoing and predictable. Therefore, the Administration proposal includes a mandatory "sunset" program that will require every pesticide product registration to expire periodically unless the products are shown to meet our constantly improving health and safety standards.

V. OTHER SIGNIFICANT RULES AND PROGRAMS

I have been pleased to find that I have come to an Agency that already has a number of forward-looking programs in place or close to implementation. I will do my best to see that these programs bear fruit as abundantly as possible.

Reduced-Risk Policy Initiative

Consistent with Administrator Browner's goal of bringing a pollution prevention focus to all of EPA's programs, the Agency is pursuing policies to promote the development of reduced-risk pesticide products in order to reduce overall risks to human health and the environment. For a variety of reasons, older pesticides may often enjoy advantages over newer, and potentially safer, products that could replace them. For this reason, the EPA has initiated a program that would encourage the registration of lower-risk substitutes for existing high-risk pesticides.

The EPA Reduced-Risk Pesticide Policy Initiative was announced in the Federal Register in July, 1992 and a public workshop was held the following October. The central idea of the reduced-risk policy is to grant priority treatment and other incentives for pesticides that can be shown to present a reduced risk to humans and the environment, relative to other alternative pesticides. The goals of this project are twofold: first, to provide incentives for pesticide producers to get troublesome pesticides off the market faster; and second, to substitute safer ones. In the place of pesticides which present unacceptable health or environmental risks, this program should promote the development, registration, and use of new lower-risk pesticides.

This July, the EPA provided registrants guidance on the types of supporting information they should provide if they believe their product will reduce risk. We have received a number of applications and we expect that some will qualify for expedited treatment.

This, however, is only a first step. To develop a comprehensive reduced-risk policy, EPA's long-term strategy will focus on three major themes: 1) developing reduced-risk criteria; 2) streamlining the registration process; and 3) initiating pesticide label reform and information outreach. We will be building on our experience with the early applicants who responded to the policy announcement to help shape a sound long-term policy.

The Administration's legislative reform package contains several provisions that would assist EPA in this effort to promote reduced-risk pesticides. First, the statute would establish explicit priorities for registration decisions, putting reduced-risk pesticides ahead of the vast majority of registration decisions. Second, it will extend the period of "exclusive use" protection for data supporting registration of new pesticides meeting the reduced-risk criteria.

The reform package also adds new authorities and streamlines existing authorities to remove from the market pesticides which present unacceptable risks. This means opening up the market faster to replacement of these high-risk pesticides by new lower-risk products.

The phase-out/phase-down provision is another tool by which the Agency could favor the development of reduced-risk pesticides. With this authority, even before cancellation or suspension of a product, EPA could place caps on the production of or other limitations on the use of pesticides which pose unacceptable risks, opening up the market, once again, to the introduction of pesticides with lower health or environmental risks.

Even the provisions which streamline label changes could enhance the ability to promote reduced-risk products. The proposed new labelling procedure would make it easier for the Agency to develop labels which impart more information to the pesticide user, such as information about which product presents less risk.

EPA Support for Biological Pesticides

I look upon recent Agency efforts to promote the registration of biological pesticides as promising. As a class, biological pesticides share a set of desirable environmental characteristics. For example, microbial pesticides (i.e. bacteria, fungi, and protozoa) tend to be effective at controlling target pest organisms without adversely affecting others; they usually do not have toxic effects on animals and people; and they do not leave toxic or persistent chemical residues in the environment.

Biological pesticides comprise the single fastest-growing segment of registration activity within the Agency's pesticide programs. Over 200 microbials and biochemicals are now on the market. In order to encourage growth in the biological pesticide market, EPA has streamlined the data requirements for biologicals and reduced the target time for processing registration applications associated with biological pesticides.

Our legislative proposal would also speed up the conditional registration process for biologicals, allowing early market entry under a time-limited conditional registration.

Worker Protection Standard Implementation

In August of 1992, EPA issued a revised Worker Protection Standard, which replaces the original Standard issued in 1974. The provisions of the new Standard will go into effect, for the most part, in the spring of the coming year. The Agency considers this revised Standard to be a great step forward in affording agricultural workers due protection from exposure to pesticides in the workplace. This provides a basic level of information and protection to pesticide handlers and agricultural workers on farms, in forests, nurseries and greenhouses. It sets requirements for training, notification, posting of treated fields, restrictions on entry into treated areas, and access to protective equipment and decontamination facilities.

I will take this opportunity to mention that, on the basis of comments received from workers advocates, we have decided to give consideration to altering one provision of the final rule -- the 30-day grace period for providing workers with obligatory pesticide training. Under the final rule as issued, a new employee could be on the job up to 30 days before an employer would have to provide them with training about the pesticides being used and how to protect themselves from exposure. We intend, through a public rule-making process, to give consideration to shortening or eliminating this grace period.

The provisions of the Worker Protection Standard will require extensive changes in the way that American agriculture operates, and these changes are not without cost to agricultural employers. The protection of agricultural workers from the hazards of pesticide exposure is an important public goal that benefits both agricultural workers and their employers.

Adverse Effects Reporting Rule (under FIFRA §6(a)(2))

In early 1994 the Agency will issue a final rule which clarifies the kind of adverse effects information pesticide registrants must submit to EPA about their products, as required under §6(a)(2) of FIFRA.

The Agency has in the past issued interpretive guidance and policy statements which left unclear the obligations of pesticide registrants to report information about adverse effects associated with pesticides. This, coupled with gaps in the Agency's data on these effects, led to criticism of this aspect of the Agency's pesticide programs.

The rule we will issue clarifies, as well as expands on the adverse effects reporting guidance issued in the late 1970s. For example, pesticide residues exceeding tolerance levels in food crops, and important ground or surface water contamination will be reportable.

Groundwater

The Agency's latest compilation of ground-water monitoring, the **Pesticides in Ground Water Data Base** (released in May 1993), shows that 132 different pesticides or their metabolites have been found in ground water in 45 states. Most detections do not exceed levels of health concern, but thirty-five pesticides/metabolites have been found in concentrations exceeding health-based reference points. At this point we are not seeing evidence of significant widespread threats to public health. For example, EPA's National Survey of Pesticides in well water found that under 10 per cent of the nation's drinking water wells showed any sign of the presence of pesticides, and only a fraction of a per cent had pesticide concentrations exceeding health advisory levels. These data do show, however, that ground water resources are being contaminated in various locations across the country.

In July 1991 EPA published Protecting the Nation's Ground Water: EPA's Strategy for the 1990s, which set forth an Agency-wide ground-water protection policy and principles. In October of that year we published The Pesticides and Ground Water Strategy embodying the Agency-wide principles in the context of pesticide regulation. The Strategy is premised on prevention, on recognizing the uniquely local character of the ground water resource, and the need to maintain the traditional state lead role in managing the resource.

Building on these strategic principles, EPA will issue several rules in 1994 to protect the nation's groundwater from pesticide contamination. These rules have been produced with considerable input from start to finish by states, as well as user, industry and environmental groups, and they are very interested in seeing us proceed with them.

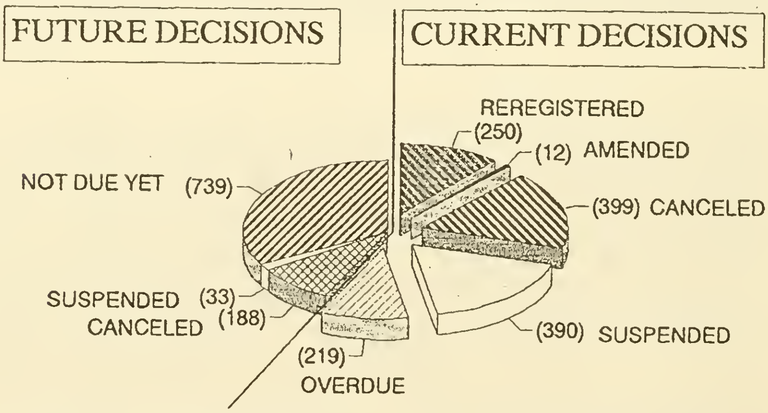
VI. CONCLUSION

In an era of shrinking budgets, all government is being called on to be more efficient in carrying out our mission. The Administration believes this is possible in the regulation of pesticides, and has laid out the blueprint for accomplishing this in its legislative proposal package. We hope Congress will consider these proposals carefully, and pass legislation which will allow us to make a good pesticide regulatory program into a significantly better one. I look forward to working with you to meet these challenges.

I would be pleased to answer any questions that you have at this time.

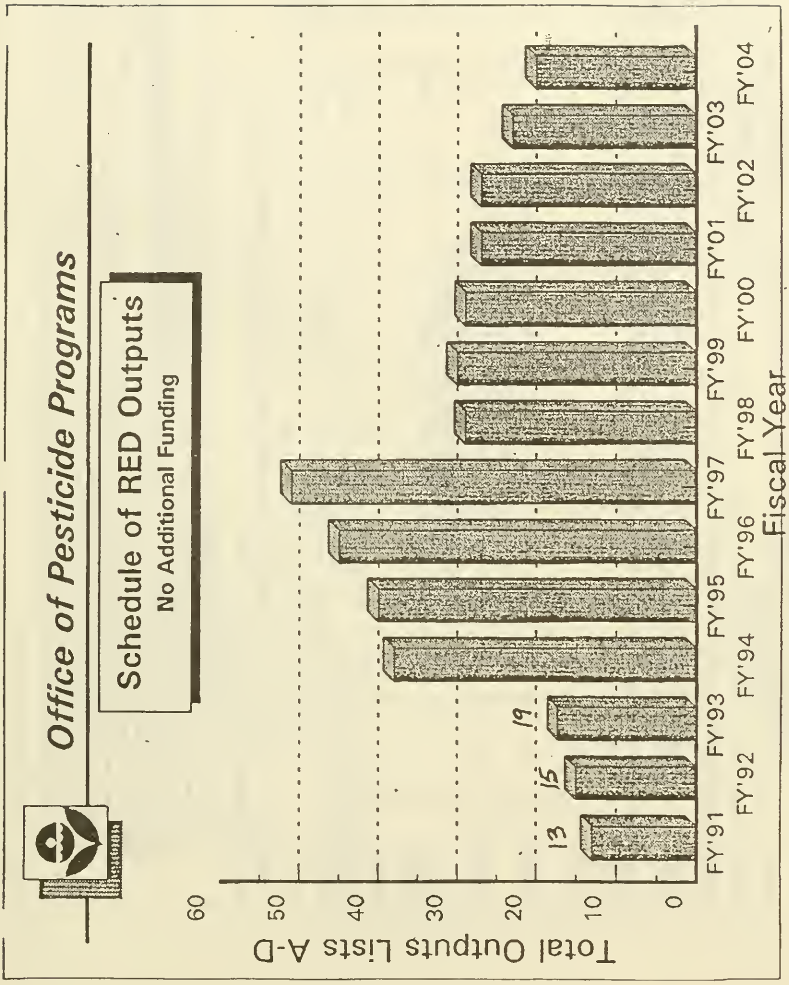
Attachment 1

PRODUCT REREGISTRATION STATUS
OF 2,237 PRODUCTS FOR 33 REDS*



* INVOLVES 50 ACTIVE INGREDIENTS. AS OF 10/7/93, EPA HAS ISSUED PRODUCT SPECIFIC DATA CALL-IN'S FOR ALL PRODUCTS/REDS ABOVE.

Attachment 2



Office of Pesticide Programs

Schedule of RED Outputs

No Additional Funding

STATISTICS FOR POTENTIALLY CARCINOGENIC PESTICIDES

PESTICIDES					"DELANEY CHEMICALS"					
A CANCER CLASS	B NUMBER REVIEWED	C NOW REGISTERED	D WITH TOLERANCES	E WITH DIETARY RISKS $>10^{-6}$	F TOTAL 408 & 409 TOLERANCES	G WITH 409s		H 409s NEEDED		I AFFECTED CROPS
						# chems	# 409s			
GROUP A:	3	2	0	0	0	0		0		0
GROUP B1:	3	2	0	0	0	0		0		0
GROUP B2:	52	26	24	21	365	4	26	8	23	31
GROUP CQ:	26	22	21	16	590	7	18	9	11	19
GROUP C NONQ:	44	40	33	NA	581	9	18	14	37	34
OTHER:	3	3	3	NA	92	2	3	2	12	7
TOTALS:	131	95	81	37	1628	22	65	33	83	91

NOTES:

"Delaney Chemicals"–pesticides which are likely subject to the Delaney clause because of concentration in processed food or feed forms.

The following notes refer to Columns A through H of the table.

A. See explanation of EPA's cancer classification system below.

B. Reviewed by OPP and/or others (e.g., IARC, CAG, and CRAVE)*.

C. Numbers now registered are approximate, e.g., voluntary cancellations due to reregistration may not be reflected.

D Includes Column A chemicals which have 408 and/or 409 tolerances, even if they are canceled, if the tolerance revocations are not yet final.

E. Numbers are approximate theoretical levels, based, in many cases, on theoretical maximum residues and include both published and pending tolerances. In cases such as the EBDCs, if their cumulative theoretical risk exceeds 10^{-6}, all are counted.

F. These numbers represent all tolerances for "Delaney chemicals", whether Delaney would force their revocation or not. This merely serves to give an idea of the number of tolerances that could be affected if one decided to eliminate the pesticides subject to the Delaney clause.

G/H. 409 needed (Column H) indicates that we have a study which shows concentration in a processed food or feed. There is some duplication of chemicals in these two columns since a chemical which already has a 409 may be found to need one for another processed food or feed; 14 chemicals appear on both lists. The total number of pesticides which appear to be subject to Delaney is 40.

I. These numbers represent the number of crops that would be affected by revocation or denial of all 409s.

Classification of these pesticides is based on a weight-of-evidence determination made generally within EPA and is in accordance with EPA's Cancer Assessment Guidelines. The classifications are as follows:

Group A: Human Carcinogen (sufficient evidence of carcinogenicity from human epidemiologic studies);

Group B: Probable Human Carcinogen
- B1: Limited evidence of carcinogenicity from human epidemiologic studies
- B2: Sufficient evidence of carcinogenicity from animal studies;

Group C: Possible Human Carcinogen
- there is limited evidence of carcinogenicity in animals in the absence of human data, including malignant tumor response in a single well-conducted experiment not meeting conditions for sufficient evidence;
- tumor responses of marginal statistical significant in studies having inadequate design or reporting;
- benign tumors where short-term mutagenicity tests are negative; and responses of marginal statistical significance in a tissue with high background rate);

Group D: Not Classifiable as to Human Carcinogenicity (either adequate evidence of carcinogenicity or absence of data); and

Group E: Evidence of Non-Carcinogenicity for Humans (no evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies)

- IARC = International Agency for Research on Carcinogenicity
  CAG = Cancer Assessment Group
  CRAVE = Carcinogenicity Risk Assessment Verification Endeavor

TOTAL NUMBER OF TOLERANCES ON THE BOOKS		
408s	409s	
8,906	216 Food	250 Feed

Mr. SYNAR. Mr. Rominger.

STATEMENT OF RICHARD ROMINGER, DEPUTY SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY LARRY ELWORTH, SPECIAL ASSISTANT FOR PESTICIDE POLICY

Mr. ROMINGER. Thank you, Mr. Chairman, and members of the subcommittee, for the opportunity to discuss with you the Department of Agriculture's activities related to pesticides, integrated pest management, and sustainable agriculture. I appreciate your longstanding interests in these subjects and look forward to working with you and others to constructively address the wide range of activities in which the Department is involved.

Under Secretary Espy's leadership, we have come a long way in a short time with our efforts in the Department of Agriculture to ensure that farming in this country is environmentally, as well as economically, sound. The interests of the environment and of the farmers who depend on that environment for their livelihoods are best served by directly addressing the potentially adverse impacts of some agricultural practices. Neither consumers, producers, or the environment are well-served by denial or defensiveness. Our approach instead has been and will be to develop progressive goals and sound programs which will enable farmers and ranchers to effectively deal with the environmental problems and challenges which confront them now and in the future.

Our efforts to grapple with the challenges posed by pesticides and pest management provide a specific example of how we should approach environmental problems. We have continued support, where appropriate, for programs which effectively address pesticide safety, the development of pest management alternatives, the transfer of innovative management systems, and the assessment of the impacts of pesticide use.

Just as important, we have changed the dynamics of the interaction between USDA and other Federal agencies such that we are now a constructive participant in developing environmental policies which affect farmers and ranchers. In particular, we have greatly improved and expanded our interaction on pesticide issues with the Environmental Protection Agency. These changes are most notably exemplified in the pesticide legislative reform proposals that were developed with the support of the White House and presented jointly with EPA and the Food and Drug Administration.

The legislative proposals we presented at the congressional hearings last month were designed to move a progressive set of reforms, provide a reasonable starting point for resolving the longstanding logjam on pesticide legislation. In addition to increasing the safety of our food supply, especially for children, our proposals provide mechanisms for timely elimination and appropriate reduction of unacceptable risks posed by certain pesticides.

From the Department's perspective, these proposals will not only improve the health of the environment and the public in general, but they also meet the critical needs of agricultural producers. In addition, these measures offer a means by which to strengthen public confidence in the food supply, which is essential to the continued success of farmers and the food market industry.

We propose to earn that confidence by establishing a single science-based food safety standard, based on realistic data that is health protective for families across the country. At the same time, we propose to intensify our efforts to develop new pest management tools and to get them into the hands of producers where they can have practical value.

As you well know, Mr. Chairman, the task we face in modernizing our pesticide and food safety laws is a daunting one. We at USDA intend to work closely with other Federal agencies and Congress to realize our goals. At the same time, we intend to move forward with important elements of our plan where we can do so consistent with existing law.

For example, we have indicated an interest in secured language in section 28 of FIFRA to establish a formal linkage between the priority-setting process for USDA's research efforts and EPA's identification of pesticides which pose particular risks or might be considered for regulatory scrutiny. Essentially, this proposal would provide a means for which the need for pest management alternatives could be used to move research efforts forward in the development of those alternatives.

This effort would ensure that risks will be reduced while also ensuring that producers have adequate methods to deal with pest problems. For USDA's part, we can begin work on this task right away by creating the data base necessary to determine the availability of pest management options. We have directed staff to bring that data base online as soon as possible, a task which was mandated by the 1990 farm bill.

The Department will also continue its programs to provide pesticide education for applicators, to assess the agricultural impacts of pesticides, to develop alternative and biological pesticides, and to transfer that new technology to producers. In conjunction with State and EPA funding, pesticide applicator training is provided through the Cooperative Extension Service for more than 400,000 private and commercial applicators each year.

This training educates pesticide applicators in the proper and safe use of pesticides and informs them of regulatory requirements such as worker protection and endangered species. The Extension Service and the Soil Conservation Service have participated in initiating a national certified crop advisor program to improve the knowledge and skills of public and private crop advisors. These measures contribute to ensuring the safe and judicious use of pesticides.

The assessment of the impacts of pesticide use requires an enormous amount of data and analysis. USDA, through the Economic Research Service, the National Agricultural Statistic Service, the National Agricultural Pesticide Impact Assessment Program, the Human Nutrition Information Service, and the Agriculture Marketing Service collect data in consultation with EPA.

Use surveys of major and minor crops are done nationally prior to ERS and NASS. The estimates of pesticide use provide information for estimating exposure levels, for identifying high pesticide usage areas, and for establishing baselines for use reduction efforts.

NAPIAP has recently been reorganized to ensure that the collection of field level information is accurate and complete. In cooperation with EPA, innovative "cluster" analysis of production methods such as the use of herbicides in corn have been initiated so that impacts across a crop from all available materials can be evaluated to determine the best means to reduce risk. Residue data are collected and reported by AMS on crops as well as on chemicals, which EPA identified as priorities in the regulatory decisionmaking.

Under Secretary Espy's leadership, USDA has strengthened its commitment to the research and development of biological and biocontrol methods which have a potential for replacing those pesticides which pose unacceptable risks and providing options where effective control methods are not available for production uses. USDA conducts research in the development of nonchemical alternatives to pesticides through programs in the Agricultural Research Service, the Cooperative State Research Service, and the Forest Service, and in methods development through the Animal and Plant Health Inspection Service.

The alternatives developed through this research cover weed, plant disease, and insect management needs. Several examples in this area are worth special mention. APHIS has developed biocontrol agents for leafy spurge, an aggressive imported weed which infests rangeland in the Western States. The release of beneficial insects has shown to be effective in replacing expensive and disruptive herbicide applications.

Cooperative work in Washington State through CSRS funding has developed epiphytic yeasts which can be used instead of fungicides to control postharvest diseases in apples. Pheromones developed through the ARS and CSRS are providing mating disruption control of such serious pests as codling moth and leafrollers. Once fully introduced, these methods can be used to substitute for organo-phosphates which pose acute risks and for which pest resistance has occurred.

Pheromones also provided nonfood use applications to control pine bark beetle on lands managed by the Forest Service. I would also point out there are many cases after Federal research has been completed, the actual tasks of delivering the products to the field has been accomplished by the private sector and these cooperative development agreements simplify the transfer.

Alternative pest methods work very well. We are working on developing alternative control measures but that is only part of our task in reducing the risks from pesticides. The Sustainable Agriculture Research and Education program has emphasized whole-farm systems approaches and grassroots involvement to devise innovative solutions. We are working to strengthen that program.

Integrated pest management programs we feel can answer many of the questions in developing programs that integrate chemical use as well as biological and cultural control methods.

[The prepared statement of Mr. Rominger follows:]

TESTIMONY
OF

RICHARD ROMINGER
DEPUTY SECRETARY
UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE

SUBCOMMITTEE ON ENVIRONMENT, ENERGY, AND NATURAL RESOURCES
COMMITTEE ON GOVERNMENT OPERATIONS
UNITED STATES HOUSE OF REPRESENTATIVES

OCTOBER 29, 1993

Thank you, Mr. Synar and members of the subcommittee, for the opportunity to discuss with you the Department of Agriculture's activities related to pesticides, integrated pest management, and sustainable agriculture. I appreciate your long-standing interest in these subjects and look forward to working with you and others to constructively address the wide range of activities in which the Department is involved.

Under Secretary Espy's leadership, we have come a long way in a short time with our efforts at the Department of Agriculture to ensure that farming in this country is environmentally as well as economically sound. The interests of the environment and of the farmers who depend on that environment for their livelihoods, are best served by directly addressing the potentially adverse impacts of some agricultural practices. Neither consumers, producers, or the environment are well-served by denial or defensiveness. Our approach instead has been and will be to develop progressive goals and sound programs which will enable farmers and ranchers to effectively deal with the environmental problems and challenges which confront them now and in the future.

Our efforts to grapple with the challenges posed by pesticides and pest management provide a specific example of how we should approach environmental problems. We have continued support, where appropriate, for programs which effectively address pesticide safety, the development of pest management alternatives, the transfer of innovative management systems, and the assessment of the impacts of pesticide use. Just as important, we have changed the dynamics of interaction between USDA and other Federal agencies such that we are now a constructive participant in developing environmental policies which affect farmers and ranchers. In particular we have greatly improved and expanded upon our interaction on pesticide issues with the Environmental Protection Agency (EPA). These changes are most notably exemplified in the pesticide legislative reform proposals that were developed with the support of the White House and presented jointly with EPA and the Food and Drug Administration (FDA).

The legislative proposals we presented at the Congressional hearings last month were designed to move a progressive set of reforms that, on balance, provide a reasonable starting point for resolving the long-standing logjam on pesticide legislation. In addition to increasing the safety of the food supply, especially for children, our proposals provide mechanisms for timely elimination and appropriate reduction of unacceptable risks posed by certain pesticides. From the Department's perspective these proposals will not only improve the health of the environment and the public in general, they also meet the critical needs of agricultural producers. In addition, these measures offer a means by which to strengthen public confidence in the food supply which is essential to the continued success of farmers and the food marketing industry. We propose to earn that confidence by establishing a single science-based food safety standard, based on realistic data, that is health protective for families across the country. At the same time, we propose to intensify our efforts to develop new pest management tools and to get them into the hands of producers where they can have practical value.

As you well know, Mr. Chairman, the task we face in modernizing our pesticide and food safety laws is a daunting one. We at USDA intend to work closely with other Federal agencies and Congress to realize our goals. At the same time we intend to move forward with important elements of our plan where we can do so consistent with existing law. For example, we have indicated an interest in securing language in Section 28 of FIFRA to establish a formal linkage between the priority-setting process for USDA's research efforts and EPA's identification of pesticides which pose particular risks or might be considered for regulatory scrutiny. Essentially this proposal would provide a means by which the need for pest management alternatives could be used to move research efforts forward in the development of those alternatives. This effort would ensure that risks will be reduced while also ensuring that producers have adequate methods to deal with pest problems. For USDA's part, we can begin work on this task right away by creating the database necessary to determine the availability of pest management options. We have directed staff to bring that database on line as soon as possible, a task which was mandated by the 1990 Farm Bill.

The Department will also continue its programs to provide pesticide education for applicators, assess the agricultural impacts of pesticides, develop alternative and biological pesticides, and transfer new technology to producers. In conjunction with State and EPA funding, pesticide applicator training is provided through the Cooperative Extension Service for more than 400,000 private and commercial applicators each year. This training educates pesticide applicators in the proper and safe use of pesticides and informs them of regulatory requirements such as worker protection and endangered species. The Extension Service and the Soil Conservation Service have participated in initiating a national Certified Crop Advisor program to improve the knowledge and skills of public and private crop advisers. These measures contribute to ensuring the safe and judicious use of pesticides.

The assessment of the impacts of pesticide use requires an enormous amount of data and analysis. USDA, through the Economic Research Service (ERS), the National Agricultural Statistics Service (NASS), the National Agricultural Pesticide Impact Assessment Program (NAPIAP), Human Nutrition Information Service (HNIS), and the Agricultural Marketing Service (AMS), collect data in consultation with EPA. Use surveys for major and minor crops are done nationally by ERS and NASS. The estimates of pesticide use provide information for estimating exposure levels, identifying high pesticide usage areas, and establishing baselines for use reduction efforts. NAPIAP has recently been reorganized to ensure that the collection of field level information is accurate and complete. In cooperation with EPA, innovative "cluster" analyses of production methods, such as the use of herbicides in corn, have been initiated so that impacts across a crop from all available materials can be evaluated to determine the best means to reduce risks. Residue data are collected and reported by AMS on crops as well as on chemicals which EPA identifies as priorities in regulatory decision-making.

Under Secretary Espy's leadership, USDA has strengthened its commitment to the research and development of biological and biocontrol methods which have the potential for replacing those pesticides which pose unacceptable risks and providing options where effective control methods are not available for production uses. USDA conducts research into the development of non-chemical alternatives to pesticides through programs in the Agricultural Research Service (ARS), Cooperative State Research Service (CSRS), and the Forest Service (FS) and in methods development through the Animal and Plant Health Inspection Service (APHIS). The alternatives developed through this research cover weed, plant disease, and insect management needs. Several examples in this area are worth special mention. APHIS has developed a biocontrol agent for leafy spurge, an aggressive imported weed which infests rangeland in western states. The release of beneficial insects has been shown to be effective in replacing expensive and disruptive herbicide applications. Cooperative work in Washington state through CSRS funding has developed epiphytic yeasts which can be used instead of fungicides to control postharvest diseases in apples. Pheromones developed through ARS and CSRS are providing mating disruption control of such serious pests as codling moth and leafrollers. Once fully introduced these methods can be used to substitute for organo-phosphates which pose acute risks and for which pest resistance has occurred. Pheromones also have provided non-food use applications to control pine bark beetle on lands managed by the Forest Service. I would also point out that in many cases after federal research has been completed, the actual task of delivering products to the field has been accomplished by the private sector through Cooperative

Research and Development Agreements (CRADAs). This delivery system provides a mechanism to quickly transfer technology into the commercial sector and into use by producers.

Alternative pest management methods take place in other forms as well. Resistant wheat strains have been developed by ARS as a non-chemical means to deal with the rapid spread of Russian wheat aphid. In some cases pesticides can be used in far more targeted applications by the use of pheromones to attract insects to pesticide stations. These methods, which ARS has developed to control boll weevils, significantly reduce the amount of pesticide used and thereby reduce the environmental impacts of control methods.

Developing alternative control measures is only part of the task necessary to reduce the risks from pesticides. Chemical and non-chemical methods are most effective and environmentally sound when used in a systems approach to crop production. Systems such as integrated pest management (IPM) are based on extensive collection and interpretation of field level data to determine pest infestation thresholds, protect non-target and beneficial species, utilize predators and parasites, and rely on synthetic pesticide use only as a last resort. USDA supports the development and dissemination of these methods through CSRS and ARS research and Extension Service education. In addition, the Sustainable Agriculture Research and Education (SARE) program has emphasized whole-farms systems approaches and grassroots involvement to devise innovative solutions to production problems. Through the SARE program. USDA also funds jointly with EPA the Agriculture in Concert with the Environment (ACE) Program, which gives priority to integrated systems projects. The Agricultural Stabilization and Conservation Service has extended the adoption of IPM through its Agricultural Conservation Program (ACP). This IPM cost-share program has now been expanded from a pilot project to encourage the implementation of nutrient and pest management methods. Furthermore the Soil Conservation Service (SCS) is making on-line systems available for advising farmers on the leaching potential of pesticides in watershed and crop management decisions. Information provided through that system will help producers make sound decisions in reducing the environmental impacts of pesticide use.

Unquestionably, USDA has made progress in providing producers with the requisite abilities to respond constructively to resolving environmental concerns. However, much work remains to be done. We must do more than simply conduct research and education programs. We have a responsibility to make sure that our programs serve our policy goals and that they actually deliver the tools to farmers so that they can meet environmental goals and economic needs. We need to take a careful look at how we set priorities in our research and extension programs. We also need a better method for evaluating the effectiveness of our programs in actually delivering tools to the field level. Not only does that kind of evaluation make common sense it is also in keeping with Secretary Espy's commitment to making sure that our efforts serve the needs of our primary customers.

Finally, we need to make sure that the pesticide-related activities we undertake at USDA are coordinated to achieve the environmental and agricultural objectives we have established.

Let me offer two examples of how we are acting to make some of the changes I have listed. In discussing our legislative proposal, we expressed our interest in setting a goal for the delivery of IPM programs on 75 percent of the Nation's crop acreage by the year 2000. We set that goal primarily as a goal for our research and extension programs. By setting and achieving that goal we will improve our ability to meet additional pesticide use and farm adoption objectives. In the Secretary's reorganization proposal, we have also taken steps to coordinate pesticide and environmental activities under the Assistant Secretary for Natural Resources and Environment by setting up the Office of Agricultural Environmental Quality, as authorized in the 1990 Farm Bill. Through this office we will be able to provide leadership for Department activities and a means to overcome organizational barriers to achieving our environmental goals. Our environmental responsibilities are diverse and pressing so it is essential that we take steps to establish a coherent and comprehensive coordinating function within the Department. We also believe that the proposed consolidation of research and extension functions will result in better program coordination and technology transfer.

Our responsibility to coordinate Federal policies and programs on pesticides and environmental issues is not limited to internal USDA policy. Our participation with EPA and FDA in the development of a joint Administration proposal on pesticide reform legislation is evidence that we are fully committed to acting in concert on pesticide issues. We know that the best and most lasting solutions will occur if we work together, not only to devise regulatory measures, but also to create better methods for solving agricultural problems. In particular, we have initiated a number of important and substantive interactions with EPA in order to respond to specific regulatory problems and to develop joint solutions to these complex problems.

Mr. Chairman, this Administration has adopted a progressive approach to specific pesticide and regulatory problems. On methyl bromide and endangered species we have agreed to work in a non-confrontational way to resolve outstanding issues in direct consultation with EPA and USDA staff. On implementation of the worker protection regulations, USDA Extension Service staff has been instrumental in devising training and outreach materials. I believe that these changes represent a significant departure from the past. They also signal a willingness to work on behalf of the public good that best serves producers, consumers, and the environment.

We are finding that this attitude also makes it possible to take on other,more complex, policy and technical issues. In response to the National Academy of Sciences study on Pesticides in the Diets of Infants and Children, technical working groups comprised of EPA, FDA, and USDA staff have been established to deal with issues such as residue and intake data, toxicology, and use reduction. In addition, EPA and USDA staff are setting up a joint task force to coordinate the research and registration efforts on biologicals. The objective of this group is to establish a direct program and working relationship between those developing biological alternatives and those charged with regulating them. Staff exchanges and the joint dedication of staff to facilitate the appropriate regulation of biologicals is intended to have significant impact on the availability of alternatives to current pest management options.

These specific interactions are in addition to ongoing collaboration among staff from EPA and USDA on minor use pesticides, IPM, microbials, and pesticide assessments. We have established a clear direction at the policy level that strong working relationships with other agencies are essential to meeting our responsibilities at the Department. In addition to setting up formal coordination groups we have also begun to develop an attitude of collaboration upon which we can build.

Secretary Espy does not believe that the interests of agriculture must be pitted against the interests of the environment, on pesticides or on other issues. The Department of Agriculture has made a deliberate decision to be a constructive player in setting environmentally sound agricultural policies. As the Secretary has stated, that means standing up for agriculture when it is doing the right things and it means standing up for change when agriculture is not doing the right things. However, we will not sit by on the sidelines, simply articulating arguments in support of the status quo.

I believe that we now find ourselves in a position where a great number of farmers are ahead of the policy makers in their desire to find and use alternatives to chemicals and in their willingness to use methods which will lead to a more sustainable agriculture. It is about time for the policy makers to catch up with those farmers. We are committed to making the changes that will bring us to that point, and we look forward to working with you and other members of Congress in getting there.

Mr. Chairman, we will be pleased to provide more detailed information on specific agency activities to you and the Committee if it would be useful. Thank you again for the opportunity to appear before you and members of the subcommittee.

Mr. SYNAR. Thank you very much.

We appreciate your testimony today.

The Chair recognizes himself for 5 minutes.

Dr. Goldman, even though most of the discussion today is going to be about food safety, I want to start with the issue that is inseparable from the larger subject, that is Benlate. As you know, the pesticide Benlate has been quite controversial, since the registrant, DuPont, paid over $500 million in claims, but later said there was never any problem with the product.

We have read that EPA has been investigating whether or not DuPont has given the agency all the required information under the adverse effects reporting provisions of FIFRA, section 6(a)2. Is EPA now satisfied that all the documents which should be submitted have been submitted?

Dr. GOLDMAN. There are a couple of problems. Really, since September 1992, the EPA has been involved in negotiations with DuPont over which documents can be provided. A couple of the areas that have been areas of contention, are the documents that involve claims adjusters and DuPont employees who gave their opinion when going out on investigations, and their own investigations of some of the allegations about whether or not there was crop damage. And the question remains whether those documents—are subject to attorney/client privileged information.

Mr. SYNAR. What is the position of EPA on that?

Dr. GOLDMAN. Our position is that these documents are reportable under FIFRA section 6(a)2, and that we should be able to review them.

Mr. SYNAR. So the answer is you don't really have all the information, and as you peel away the information you have been given, there is more to ask about; is that correct?

Dr. GOLDMAN. Yes.

Mr. SYNAR. Does the agency need additional investigative authority to ensure that the pesticide companies are not withholding anything from EPA?

Dr. GOLDMAN. I think that in general the agency does need additional authority. And actually some of these authorities are part of our proposed legislative package.

Mr. SYNAR. Let me ask you this. If current law does not allow FIFRA inspections beyond the loading dock, that is until a pesticide is made, that prevents EPA from inspecting the manufacturing process; is that correct?

Dr. GOLDMAN. That is correct.

Mr. SYNAR. If EPA discovered that a company withheld crucial information that should have been submitted, the maximum penalty nonetheless might be as low as $5,000 since the maximum civil penalty is that under FIFRA. Should those penalties be raised?

Dr. GOLDMAN. We believe those penalties should be commensurate with the magnitude of the violation and that they should be similar to the kinds of penalties that can be levied under other environmental statutes.

Mr. SYNAR. Now, in the case of Benlate, EPA has had to use tax dollars to pay to get the documents used as exhibits at trials, documents that were not submitted by DuPont; is that correct?

Dr. GOLDMAN. That is correct.

Mr. SYNAR. Now does that experience with Benlate indicate the need for additional enforcement authority to get compliance with adverse effects reporting requirements?

Dr. GOLDMAN. I believe that it does, yes.

Mr. SYNAR. We have heard also that there are now fears that Benlate can cause human health problems. Apparently, some researchers in Britain have claimed that Benlate might have caused a cluster of severe birth defects, of causing babies to be born blind, even being born without eyes. Has EPA or any other government agency begun investigating the possible health effects of Benlate?

Dr. GOLDMAN. The National Institute of Occupational Safety and Health [NIOSH] is looking at that in Florida. We have been doing some investigating of some of the claims that we have been hearing. And we do know from looking at the animal studies, study of teratogenicity or creation of birth defects, that this particular type of birth defect is associated with Benlate, but what we don't believe is that anybody is exposed to levels that would be high enough to cause such effects.

Mr. SYNAR. When will the results of those investigations be completed?

Dr. GOLDMAN. We are expecting results from NIOSH within a matter of months.

Mr. SYNAR. Let's get back to the issue of reregistration. I have before me here, you have obviously seen it, the most recent or latest progress report issued by EPA. Of the products listed in page 20 and 21 that you have reregistered, 87 percent of those, Dr. Goldman, are for sulphur, which has been used for literally hundreds of years. These are bleaching chemicals or swimming pool chemicals. Can you tell us when EPA is going to start looking at important pesticides in reregistration?

[Reference is made to EPA pesticide reregistration report, April 1993.]

Dr. GOLDMAN. Actually, my understanding is that the current REDs under review are for active ingredients for products that are on what we call list "A." And that what happened with the program was because of the delays in startup and problems with study rejection, that it just happened that the initial complete packages that were assembled were not all list "A's," but were instead some of the compounds that are on our list "C" and "D." But now as complete packages are cued up in the process, we will follow the prioritization scheme and go after those list "A's" first.

Mr. SYNAR. Mr. Mica, for 5 minutes.

Mr. MICA. Dealing with the Benlate questions that were raised by the chairman, I have a copy of the statute here and I am wondering if the problem is whether we need to clarify some of the language or that the EPA needs more enforcement power. What is your opinion on this?

I think that information is required. It says: Factual information as it is outlined here. Should we be clarifying the language rather than giving more enforcement power, or what is your opinion on this particular?

Dr. GOLDMAN. I don't think it is either/or. I think that both of those issues have arisen.

Mr. MICA. But what about the way this is now written as far as factual information versus opinion?

Dr. GOLDMAN. Well, the problem is that the attorney/client privilege has to be protected. And then it is a matter what information falls under that category. For example, does an insurance claim adjuster report constitute attorney/client privilege?

Mr. MICA. You don't think we could just clarify the language?

Dr. GOLDMAN. Well, we don't think that it does. We think we can resolve that one. But then there is a further issue of what if all investigations by companies were done by their attorneys and as a part of litigation; then we would never be able to have access to key information. And so I do think that particular issue, some of that is language clarification, some of that needs to be negotiated out. I also believe that we need stronger enforcement.

Mr. MICA. You probably believe it would be better to give EPA some additional power to go in and conduct some fishing expeditions. I don't want to spend all my time on that, because that is one thing that has driven us crazy in Florida, and you all give us so much on our platter that I asked the chairman for an hour, which he has denied me, but you are new in your position and I don't want to jump on your case, but you have an assistant here. Let me tell you what is going on.

Dr. GOLDMAN. I am going to clarify, this is not my assistant; this is the Deputy Commissioner for Policy from the FDA.

Mr. MICA. That is right, but your associate, I should say, is with you. And let me just tell you what is going on out there, what we have to deal with as Members of Congress.

I have got several cases, I mean, we just left one, let's go to another one. We have got a small company that is struggling to survive in my district, and called Dial Medical. It submitted an application for expedited review in February 1992. The EPA information that was given to them, and I have got a copy of it, promised results within 90 days. They received from EPA—and I have got a copy of it, I will submit it for the record here—this letter informing them: "Your submittal was found to be in full compliance with the standards for submission of data contained. . . ." This was September 1992. In 1993, EPA informs them they have changed the rules of the game.

[The information can be found in the appendix.]

Mr. MICA. In August, I went over to see your associate, who wasn't there, and hand delivered a letter asking for some action on that case. September 21, they responded to me and said that additional testing is needed and the application will be completed in 1994. I went ballistic.

Of course, during my visit, your associate wasn't there—and we had a window smashed in your parking lot while a bunch of guards sat in the lobby and smoked cigarettes and drank coffee. But that is another subject we won't get into.

Can you imagine my frustration? Now, that is my frustration. Now these poor people have spent $25,516 preparing the product for registration, $25,368 in 1993 updating, $11,700, totaling $62,637. So far they have lost $926,000 on the project, and they are looking at $1.125 million in lost revenue over the second 9 months.

This is the way this place is operating. And it is driving people crazy. It is driving me crazy. That is why I am going to be on your case every week. That is why I have been on EPA's case every week.

Shall we go to another one?

How is my time, Mr. Chairman?

Mr. SYNAR. Mrs. Thurman, then we will be back to you.

Thank you.

Mr. MICA. Thank you.

Mr. SYNAR. Mrs. Thurman.

Mrs. THURMAN. Well, Dr. Goldman, I also am from Florida. You have the Florida group up here, so I should probably yield some of that time back to him.

However, I need to ask some questions as well, and also to Mr. Rominger, particularly. Maybe you both can answer this because it is a very important issue for Florida. It deals with methyl bromide.

Our farmers are starting to hear rumors that EPA is out to get them and are out to get this particular fumigant, and they are becoming very restless. They have also been listening to some comments that have been made to the point where, if it is gone, that is just tough. Well, for those farmers, that is tough. And it is also—we have been given, an indication that people believe this is just used on turf grasses and luxury crops, which is absolutely not true. They use it in 100 different crops.

I can tell you that in Florida, both with our citrus and vegetable people, this is a mainstay for them. We heard testimony in the Agriculture Committee, specifically dealing with this. There was a statement made that there was scientific consensus on this issue.

Just yesterday, I understand scientists got together and they are really not sure just how it affects all of this. So I am not sure that, in fact, that all scientists agree with this, or as far as the ozone issue. So, Dr. Goldman, what kind of assurances can you give my farmers and me that EPA will not proceed with banning this?

Dr. GOLDMAN. None at all. At this point in time, the EPA has very serious concerns about the use, not only of methyl bromide, but also other chemical agents that are destructive of the ozone layer. This is a very serious issue for all of us. We are in a very tenuous balance right now between the numbers of chemicals that have been used over the past several decades, in our ignorance, our lack of knowledge about what was going on in terms of chemical reactions high, high up above us. And it is now very important for the United States to take the leadership role in the world to phase-out the use of these chemicals. Obviously, if a case could be made methyl bromide were not one of these chemicals, it would fall off of this list.

The EPA also is very concerned about the needs of farmers to have the products that they need in order to be able to do their business. And we do consider that to be part of our responsibility. And I think that the new working relationship between the EPA and the USDA, in terms of really working closely together on these concerns, will go a long way toward making sure that we mitigate the impacts.

And I do not at all consider this to be a minor issue. I think it is very important that we work closely together to do this.

Mrs. THURMAN. Mr. Rominger, then let me ask you; how is EPA working with you on this? Because it is my understanding that USDA has been sort of a supporter, in some ways, of this particular fumigant. Can you give us some ideas of what kinds of information they are asking from you, what kinds of scientific reports they have received, any of that that they have been involved with?

Mr. ROMINGER. Well, we have been involved with EPA on this issue. And I should go back to the beginning, the Montreal Protocol and the agreement at the United Nations that the U.N. environmental program would continue to look at the research and do additional research on methyl bromide and that within 2 or 3 years, we will be able to take another look at just how serious an ozone depleter methyl bromide is.

Second, of course, the Clean Air Act is more restrictive than the Montreal Protocol, so EPA has to follow that. And we have been providing information to EPA on the benefits that methyl bromide has provided in agriculture and certainly it is a major chemical to——

Mrs. THURMAN. Excuse me. Are benefits a part of any report that you give? Is that taken into consideration?

Dr. GOLDMAN. Under the Clean Air Act, and in dealing with this particular problem, there are no benefits considerations.

Mrs. THURMAN. Mr. Rominger, I am sorry, I didn't mean to interrupt.

Mr. ROMINGER. We compile the benefits for our use and provide them to EPA, whether they can use them. It is an important chemical in two major areas; one, in soil fumigation, and two, in the postharvest treatment of products, so that they can pass through quarantine, our exports to other countries.

Mrs. THURMAN. Mr. Rominger, on that point, is there not a letter from Japan stating that if we do not use this that they will not accept those imports?

Mr. ROMINGER. I haven't seen that letter, but Japan certainly has raised that issue. And Japan is not the only country that has indicated that if we are unable to provide satisfactory postharvest treatment, they won't accept many of our products. So we are mounting a very vigorous research program to find alternatives for methyl bromide.

Secretary Espy worked with EPA early on to achieve the agreement that we would not have a phase down in the use, that the chemical will stay in use until the year 2000. And we hope that gives us the time to develop these alternatives. Again, we have increased our research budget to look for alternatives for methyl bromide.

Mr. SYNAR. The gentlelady's time is expired.

Mrs. THURMAN. Thank you, Mr. Chairman.

Mr. SYNAR. Dr. Goldman, let's focus now, if we can, on the food safety plan. As I said in my opening statement, I think we are off to a good start. But very frankly, as we have been told there are many unanswered FIFRA-related questions.

Let's start from the very beginning. Given the 1992 court decision requiring strict enforcement of the Delaney clause, do you have an effective reregistration program without amendments to the statute?

Dr. GOLDMAN. No, the court decision does not take care of the concerns, all the concerns that we have.

Mr. SYNAR. So you do need amendments to the statute?

Dr. GOLDMAN. We do need amendments to the statute.

Mr. SYNAR. Now, EPA has provided in its testimony this morning a chart, with which you are familiar, which is an update of the list of cancer-causing pesticides, those that would need section 409 tolerances. Now, the ones that I am particularly interested in, too, are the human carcinogens in group B–2. That list indicates that there are 21 cancer-causing pesticides which, assuming maximum exposures, do not meet the one-in-a-million risk standard.

Dr. Goldman, under the administration's proposal, what will happen to those 21 pesticides?

Dr. GOLDMAN. Either they will have to show that they can meet a lower standard, because this is, after all, a theoretical number based on the maximum tolerance allowable, or they will not be able to have the tolerance.

Mr. SYNAR. So if we don't amend the statute, how many pesticides currently with section 409 tolerances or meeting 409 tolerances are subject to immediate revocation?

Dr. GOLDMAN. I can't answer that question without rifling through a lot of paper here.

Mr. SYNAR. All right. Will you provide that for the record?

[The information is filed for the record in the subcommittee office.]

Dr. GOLDMAN. Certainly.

Mr. SYNAR. Now, for any of those needing 409 tolerances, Dr. Goldman, but not having them, any processed foods containing pesticides could be subject to condemnation at any time; is that not technically correct?

Dr. GOLDMAN. I am sorry, could you repeat that?

Mr. SYNAR. Processed foods, subject to 409 tolerance, could be subject to condemnation at any time.

Dr. GOLDMAN. That is correct.

Mr. SYNAR. So the food industry is playing Russian roulette by simply assuming that no State or Federal official is going to pull the products off the shelf, because a judge could be petitioned and do so, and be pulling things off the shelf through an order, could he not?

Dr. GOLDMAN. That is correct.

Mr. SYNAR. All right. Is there any way to avoid that problem without amending the Food and Drug Act?

Dr. GOLDMAN. Not that we can see.

Mr. SYNAR. What you are proposing, if I understand it correctly, is to replace the zero-risk Delaney clause with a "narrative" risk standard which does not explicitly define what you mean is an acceptable or, "negligible risk." Why not a so-called firm, brightline, a specific, quantitative standard, so that we will all know who is good and who is bad?

Dr. GOLDMAN. We believe that the administrative history on the use of that term, "a reasonable certainty of no harm," is very clear and has been clear through a number of different administrations. We do not want to be locked into a brightline standard which could at some point in the future not make sense or not be relevant in the light of new procedures that we might be using to assess risks.

Mr. SYNAR. Well, we respect changing science. What we fear is changing administrations. What happens to flexibility if another John Todhunter, known as the Frank Burns of toxicology, takes over the program and reads flexibility to mean that nothing needs to be regulated.

Dr. GOLDMAN. I understand your concerns about that, but I think if you are in that situation, then you are in a situation where it almost doesn't matter what is written in the statute.

Mr. SYNAR. But isn't flexibility the problem of why we don't have any special review started for 5 years and why the high-risk tolerances have been on the books for years?

Dr. GOLDMAN. I believe that the problem with special review has been more of a problem of resource limitations, and not a problem of lack of will to address some of the risks.

Mr. SYNAR. Let me ask you this; after 6 months, will you all be able to identify all the high-risk tolerances?

Dr. GOLDMAN. We have said that we could and I believe that we can.

Mr. SYNAR. So you could determine the list now; is that correct?

Dr. GOLDMAN. We could determine a tentative list at this time. I think that we would want to do a considerable amount of background work over a several month period of time to make sure that it is absolutely correct.

Mr. SYNAR. Dr. Goldman, you are on notice today, October 29, 1993, 6 months to this day, we want that list. That way, if we enact legislation sometime next summer, you will at least have a few months ahead of the game.

Now, are we going to have that list 6 months from this day?

Dr. GOLDMAN. I think we can do that. I will get back to you about that.

Mr. SYNAR. Under the administration's new plan, if there is an unacceptable risk, you would provide 5 years to reduce this pesticide risk——

Dr. GOLDMAN. Could you ask that again? I am sorry.

Mr. SYNAR. Under the administration's new plan, if there is an unacceptable risk, you would allow 5 years to reduce the risks of the pesticides, and/or help the growers find alternatives; is that not correct?

Dr. GOLDMAN. Only in a situation in which more immediate action would produce very large dislocations.

Mr. SYNAR. Have you sat down with the USDA to come up with a plan to do this?

Dr. GOLDMAN. We are working closely with the USDA on this.

Mr. SYNAR. I didn't ask you that. I asked you if you have a plan with the USDA to do this?

Dr. GOLDMAN. We do not have a detailed plan in place for doing this.

Mr. SYNAR. And the tolerance reassessment will also be a health-based standard, which is, the "reasonable certainty of no harm" standard. Where did that standard come from?

Dr. GOLDMAN. Mike, do you want to address that?

Mr. TAYLOR. Mr. Chairman, this is the standard that currently exists in the Food, Drug, and Cosmetic Act of positive food additives and color additives. It is the basic safety standard that we use to assure the safety of all the chemicals that are used to grow— or I should say, to process food.

The thrust of our proposals for pesticides is that pesticides should be subject to the same health-based safety standard as other chemicals used in food processing.

Mr. SYNAR. So this is a standard that food companies have known and lived long and profited by for a long time; haven't they?

Mr. TAYLOR. This standard was adopted by Congress in 1958, and we have been implementing it successfully and finding chemicals safe under the standard, and also being able when chemicals have not met a solid health-based standard, we have been able to take chemicals off the market.

Mr. SYNAR. Let me ask this; if the tolerances are authorized under the Food and Drug Act using only a health-based standard, but FIFRA registration approval remains a risk-benefit standard, could there be a conflicting standard between statutes?

Dr. GOLDMAN. I think that it would not be a standard that would be in conflict. I believe that it is appropriate to employ a different standard for residues in food than for other hazards that may be of concern. And the reason for this is because I believe that the consumers expect that if they are being asked to assume a risk from something in food, that they themselves would be the ones to benefit, not others.

Mr. SYNAR. Dr. Goldman, one point raised by the recent and past GAO reports, is that the pesticide program has found it impossible to get reregistration on track after 20 years of trying, and yet the administration proposal would have you identify and evaluate high-risk tolerances within 3½ years. What confidence should we have that you are going to meet these deadlines, since none of the other deadlines in the last 20 years have ever been met?

Dr. GOLDMAN. I think that there should be a lot of confidence along those lines. First, the proposal that we put forward shifts the burden to the registrants to provide the information that the tolerances are safe. If they cannot prove to the agency that the tolerances are safe within the timeframe that is required, the tolerances will expire. That is very different than the process that we have in the reregistration program.

Second, and since what we are doing by proposing, looking at the tolerances first, is cuing up the set of studies that apply to food-use risks first. And when we talk about completion of reregistration, we are talking about evaluation of a lot of other studies as well.

Third, we have already made the food-use pesticides priority "A" pesticides. And so these are the pesticides that we have already been cuing up to look at first. So I do believe that this is a credible proposal.

Mr. SYNAR. Mr. Mica.

Mr. MICA. First, can you respond, Dr. Goldman, to my question about whether this is going to be "business as usual" with the agency or is there a plan? I mean, should we just tell people to forget it when you say 90 days?

Dr. GOLDMAN. I think there are—it is going to be very important for me to pay attention to making sure that we have total quality management in my part of the agency and that we are paying attention to our customers when they come to us with problems, like the problem that you mentioned. And I also——

Mr. MICA. You are committed to that, you are committed to that?

Dr. GOLDMAN. I also really can't comment on the individual case.

Mr. MICA. No, I am just picking—you know, this is just one small case, but it is the way the whole agency is run. It is the way things are conducted there as far as business.

Dr. GOLDMAN. I will say, Mr. Mica, that the costs that you mentioned for testing that product, from the perspective of thinking about the eventual use of this as a sterilant, which means to sterilize instruments and other equipment that will be used for medical and other purposes, or, you know, other sterilant functions that protect the public health, that does not sound like too much money to spend for the testing.

Mr. MICA. Well, it would replace formaldehyde, and I think we all know the problems with that substance. But let me go on, if I may. Let's talk about your testimony that the problem is resource limitations. The IG and GAO said EPA has no plan, management, and limited resources or resource limitations. The IG said he hadn't seen parts of the plan. For example, in the information management areas, there was an entire hearing about the disaster in there. He said he hadn't seen something; you said you prepared something. Who is on track here?

Dr. GOLDMAN. I believe that the program is on track with information management systems.

Mr. MICA. You have a plan, and he has seen it? Did he not just tell me the truth?

Dr. GOLDMAN. I believe that perhaps they are waiting for an official communication from the agency. And I am not really sure what the status is on that.

Mr. MICA. When you go back, tell the administrator we are waiting, too. Who are you all working with in the White House to develop our national EPA?

Dr. GOLDMAN. One thing I might want to address is that I think that there may be a mixing here of two different information systems. Within the pesticide program to support the reregistration efforts, there is an information system in which we have invested, I think, somewhere between $10 and $15 million.

Mr. MICA. And within the agency, we have a $300 million problem.

Dr. GOLDMAN. Within the agency, there is a different problem, which I can't really address.

Mr. MICA. But they all seem to be in sort of disarray. So we are looking forward to some resolution.

Who in the administration is the point person in the White House dealing with the EPA policy nationally?

Dr. GOLDMAN. There—there are a number of people.

Mr. MICA. Who is taking the lead? Who is taking the lead?

Dr. GOLDMAN. Katie McGinty is probably the person who is——

Mr. MICA. And do you consult—have you consulted with her on some of these issues?

Dr. GOLDMAN. We consult with the White House on some issues.

Mr. MICA. But have you consulted with her?

Dr. GOLDMAN. Most of my work has been with the Domestic Policy Council.

Mr. MICA. Is the administrator then consulting with her?

Dr. GOLDMAN. Absolutely.

Mr. MICA. So she is really the focal point for developing this policy; is that correct?

[Witness nods head up and down.]

Mr. MICA. OK. Another question relating to some concerns producers have in my State. We just heard the question about methyl bromide. If we conducted a phaseout, wouldn't you adversely affect the food supply and exports? There is quite a substantial list of uses—agricultural commodity uses. What would happen here?

Dr. GOLDMAN. One thing I should first say to direct an earlier statement I made, is that within the Clean Air Act, and I am sorry that Mrs. Thurman is not here, there is a consideration of the benefits side. And I think that there is a fair amount of flexibility in exactly how the agency takes action there.

Mr. MICA. Let me jump to another area.

In my district, agriculture producers are concerned that EPA's position on the Delaney clause may keep plant protection products from being registered or reregistered. I would like a clarification as to the agency's interpretation of the Delaney clause. I am concerned that as you identify detectable residues or metabolites, if that is correct, you consider it a Delaney clause issue.

However, if you have undetectable residues or metabolites, does your agency then consider that there is none of the compound present or do you still consider that the Delaney clause is in effect because the scientists can't say with total certainty that there is no residue or metabolite present?

It is my understanding that the registration of a critically important pesticide, and the technical name, correct me if I am wrong, is diflubenzuron, or micromite, is being delayed under these circumstances, and specifically Florida has been waiting for 12 years to complete a registration for use of this substance against the citrus—citrus weevil.

Dr. GOLDMAN. I can't speak specifically to the pesticide that you mentioned.

Mr. MICA. Can you give a response?

Dr. GOLDMAN. However, how we interpret Delaney, we think it pretty literally says that to fall under Delaney, the pesticide must concentrate in the processed commodity compared to the level that is allowable on the raw agricultural commodity, and which therefore means that the residue must not only be detectable but it also must be at a higher level in the processed commodity than it would have been allowed to be in the raw agricultural commodity.

Mr. MICA. It is my understanding that you have testified that we need a legislative remedy here, and I also—relating to some interpretations of the Delaney clause vis-a-vis the court decision—it is my understanding a petition has been filed that suggests that EPA could address the Delaney clause without legislation. It is referred to, I guess, as a flowthrough provision. Could you tell me the status of that petition?

Dr. GOLDMAN. It is still under consideration and some of the factors that we must consider, first, the practicability of the proposal. Many growers tell us that at the time that they grow their commodities, they do not know what the destination of those commodities is going to be, whether they are going to the fresh market or the processing market, and so, you know, we must have in place a system that makes sense in terms of the enforcement capabilities of the FDA.

We also have a fair amount of precedent that we need to look at and not only the statutory language, but any information we can get about the original intent of those who wrote the statute.

Mr. MICA. When do you think you will have a decision on the petition?

Dr. GOLDMAN. I think we are looking at a matter of just a couple of months on that at most.

Mr. MICA. I will yield back, Mr. Chairman.

Mr. SYNAR. Ms. Goldman, let's go back to food safety. I told you this before. One of the biggest disappointments I see in your proposal is the circle of poison provisions. For the life of me, I cannot understand how the Clinton administration offers us so much less than the pesticide industry was willing to offer us in the past. The proposal only forbids the export of pesticides banned here for health reasons and requires a method of detection for unregistered compounds. Would you like to explain to me the limited restrictions on unregistered pesticides in your proposal?

Dr. GOLDMAN. I think there are a couple of issues. One is that I think that as Administrator Browner said when she appeared before you about a month ago, we do need to have discussions with Congress about the circle of poison provisions and we do need to work with you some more on that issue.

Mr. SYNAR. It might be important if Ms. Browner went to see the Vice President since he was the cosponsor of this legislation in the Senate and Mr. Leahy, because the three of us have really been the fathers of this thing and, obviously, having worked for Vice President Gore at one time, Ms. Browner might find it interesting to talk to him about what he thought "circle of poisons" should be.

Dr. GOLDMAN. The second thing I want to mention is I do think this proposal is stronger than the proposals that you heard from the last administration, and that in terms of what we would look at for scope of cancellation, would look at not just cancellation for all uses but also for virtually all uses. This was an issue in the last administration.

Mr. SYNAR. Let's look at your "reduced risk," or "safer" pesticide, proposal within the food safety plan. How do you envision making it easier for a new product known to have a low risk to displace an existing product that has obviously higher hazards?

Dr. GOLDMAN. I think that for many of these for biologically based products, that we can make a scientific determination up front about whether or not they are likely to fall into areas where we are going to encounter risk. I will use one example: Pheromones, where we know that those are agents that are very target certain, even within insect species. So what we are looking at is ways to speed an initial registration for those still requiring the complete test package, but allowing the registrant to begin to market the product while that more complete testing is being completed.

Mr. SYNAR. Can't you just announce and cite the "safer" ones versus the other ones?

Dr. GOLDMAN. Can't we just announce them?

Mr. SYNAR. And cite the difference.

Dr. GOLDMAN. I think it is important that we be required to make some kind of a scientific determination because I think this is one area where, frankly, you don't want to give the agency too much flexibility. You want to make sure that we are making that determination based on good science.

Mr. SYNAR. Do you need legislative authority or can you all do this in clear language so that it is just not rhetoric?

Dr. GOLDMAN. There is much that we can do administratively, but I think with legislative authority, we can have a much stronger package. One of the things that we would like to do that I think probably requires legislative authority is to give the registrants an extended period of exclusive use of the data that they develop. We think this provides major economic incentive to the companies.

Mr. SYNAR. No small or large companies are going to spend $40 to $60 million trying to find a better mousetrap if the old pesticides are going to be able to stay out there; are they?

Dr. GOLDMAN. I think that is why the two parts of our legislative package are inextricably linked, because we need to have both the ability to get rid of bad actors when they are there, or scale down their use and to encourage better products.

Mr. SYNAR. Let's talk about that phase down. The administration plan says that they are proposing this phase down for the old bad actors. Now, I can't figure out how that is supposed to work other than it is supposed to scare the stuffing out of the pesticide companies which see it as a vaguely defined tool, somehow eliminating the undefined conditions. Tell me and tell the gallery behind you, what is this all about and what are they supposed to do?

Dr. GOLDMAN. Well, first, a scientific determination would need to be made that there is a reason to believe that there are serious risks associated with a pesticide.

Second, we would use due process and, frankly, I think part of what inspired our asking for this provision is exactly the problems that have occurred with the special review process, that either nothing is happening or when things are happening, they are happening out of the eyes of the public. This would be a way to do this very publicly and out in the open, where there could be participation and due process, and that is really what we are talking about.

Mr. SYNAR. One last question. As a pediatrician, you are probably one of the most qualified in the administration to respond to this question: Does the proposal encompass the recommendations from the National Academy of Sciences?

Dr. GOLDMAN. Yes, it does and there are a number of specific provisions that I didn't get to today.

Mr. SYNAR. You understand people argue that some of the recommendations in the report are not being applied; you are sensitive to that?

Dr. GOLDMAN. I think that we have included everything in our proposal that can be done at this time. I believe that there are recommendations from the National Academy of Sciences report that need to be addressed through pushing forward the science in this area. We are not ready to just say, oh, now we have the gadget that we can use to address this. We have got to invent that gadget.

Mr. SYNAR. Mr. Rominger, what specific mechanisms will there be for EPA regulators to put problem pesticide uses on the agenda of the USDA so that the solutions can be found?

Mr. ROMINGER. We are setting up a working group at the USDA and EPA, and we are also asking that the section 28 language specifically state what should be required, that when EPA determines that a chemical is on that list, it would trigger increased research efforts at USDA. So we want to have a very close working relationship there.

Mr. SYNAR. Let's go through an example: Assume that EPA's review shows an unacceptable risk from a certain pesticide on a certain crop in a certain State or region, and assume that the pesticide companies with an obvious self-interest, insist there are no alternatives, and they get the farmers all whipped up that the bureaucrats are going to put them out of business because of a few dead mice. Is your staff, along with the EPA folks writing the legislation, going to present a plan which can show how, during a 5-year transition period, the Department, working with these grower groups, university researchers, will develop alternatives?

Mr. ROMINGER. Yes. I think we would. I think methyl bromide is probably an example. We have had meetings with researchers from all over the country to assess what the status of the alternatives are, and we could do the same thing for a new chemical that comes up, a new one that was going to be taken off the market. We would look at all the research that is going on now, and see where the gaps are, and what we would need to do to come up with satisfactory alternatives.

Mr. SYNAR. So you are going to provide us that plan so we can review it?

Mr. ROMINGER. Yes, we will.

Mr. SYNAR. How will the Department get newer and safer products, such as biological pesticides, into the hands of farmers more quickly, Mr. Rominger.

Mr. ROMINGER. We are working through our IR4 program to develop the data where there are data gaps in getting a registration for safer or biological pest controls, and we are increasing the funding in that program.

Mr. SYNAR. So how do they get it to the farmer?

Mr. ROMINGER. We work through the Extension Service to get that information to farmers, as well as other information networks.

Mr. SYNAR. Are Extension Service officers still allowed to make speeches for money for pesticide companies?

Mr. ROMINGER. I am sorry, I didn't get the question.

Mr. SYNAR. Are extension agents allowed to make speeches for pesticide companies?

Mr. ROMINGER. Are they allowed to make speeches for pesticide companies?

Mr. SYNAR. On behalf of pesticide companies.

Mr. ROMINGER. Not that I am aware of. But we don't control directly, as you know, the extension agents out in the country. They are the employees of the State universities or in local government, but we certainly, through our program, are trying to get the information to them that we believe they should be talking about.

Mr. SYNAR. Is 5 years long enough to develop the alternatives to the problem?

Mr. ROMINGER. Well, we can't guarantee that in every case. I think we have had some examples, like the Russian wheat aphid, where we have been able to find control measures. We have others like the sweet potato whitefly right now that we are not sure we are going to have adequate control methods within 5 years. But that is really not a case of a pesticide going off the market. We are looking for a control for a new pest. So we think that, in most cases, it would be enough.

Mr. SYNAR. You have signed off on a proposal which would use only a health-based standard for evaluating pesticide tolerances. As you know, in some agricultural circles, that is an evil concept. In a sense, many think that means that for very little certain risk, the standard might eliminate the consideration of benefits in EPA's evaluation. What do you say to those people who say that it is impossible and unnecessary?

Mr. ROMINGER. We say that health-based risk will include consideration of a significant disruption in the food supply, and that is a health-based risk to the public if we are going to eliminate a major fresh fruit or vegetable. Those kinds of things will be taken into consideration.

Mr. SYNAR. Let's look at the sustainable agriculture efforts at USDA. GAO, in 1992, Mr. Rominger, found that you were underfunded, uncoordinated, and fragmented. This is to me due to a lack of past management support and generally a bad attitude down at the Department. Are we going to see a change under Secretary Espy?

Mr. ROMINGER. Yes. I think we have already seen a change. We are interested in moving forward on sustainable agricultural programs, and, in fact, I was at the conference in Seattle last weekend, the worldwide sustainable agriculture conference, and we are supporting that program.

Mr. SYNAR. Let's look at that. The sustainable agricultural research program (SARE) receives somewhere in the neighborhood of $5 million out of a research and education budget of over $1 billion. Now, I know money is tight, but is that a commitment?

Mr. ROMINGER. Well, that is a specific program that has been budgeted by Congress, and we have asked for increases in that program. There are other parts of our research program where we certainly are researching areas that I think would fall under the general termination of sustainable agriculture, but these just don't happen to be part of this specific program.

Mr. SYNAR. One of the administration's proposals include recordkeeping on all the pesticides to provide EPA with better information. We started that effort, as you know, in 1990 with the farm bill. Is this going to help or is it going to correct the past recordkeeping problems?

Mr. ROMINGER. We think it will help, that we are improving what was done in the past and we are adding the additional chemicals and recordkeeping because we want to be able to give EPA valid data so that they can make a good risk analysis, so that we will have the data on what percentage of the crop is being treated, so that they can determine tolerances based on actual data rather than using a default that the whole crop was treated at the maximum rate.

We don't think that serves the purpose of farmers. We want to find out exactly what they are using and this is a way to do it. They will keep records. This does not include reporting by them. We will gather the data through our surveys of the farmer records.

Mr. SYNAR. The administration's food safety package also includes a commitment to having 75 percent of the acreage using integrated pest management techniques by the end of the decade. Mr. Rominger, since we don't know or we don't want to see some later discovery and most production is already using IPM, so that we don't need to change the status quo, can you provide this subcommittee with an estimate on how much of the current production uses IPM techniques under your definition?

Mr. ROMINGER. We have an estimate on that at the present time. We think it is somewhere around 20 percent.

Mr. SYNAR. You don't have any idea, do you? It is just an estimate; right?

Mr. ROMINGER. It is an estimate, an average. With some crops it is as high as 80 or 90 percent.

Mr. SYNAR. When will you know the actual figure?

Mr. ROMINGER. I don't know how long we will take but we can certainly work to get the figure on that.

[The information can be found in the appendix.]

Mr. SYNAR. One last point. Since we have been given oversight jurisdiction over you now, can you provide us a detailed listing of the programs and budgets of who does what regarding pesticides within the Department?

Mr. ROMINGER. Yes, we can. We will.

[The information can be found in the appendix.]

Mr. SYNAR. Mr. Mica.

Mr. MICA. Mr. Rominger, how long have you been with the Department of Agriculture?

Mr. ROMINGER. It has been about 7 months now.

Mr. MICA. Mr. Rominger, in that 7 months, have you lied to a Member of Congress or purposely misled?

Mr. ROMINGER. No, I have not.

Mr. MICA. I am going to ask you here for the record to provide me by November 15, a diary of where you were in your conduct on September 8 and September 9, and if you don't provide that for me, I will request a Freedom of Information Act.

Mr. ROMINGER. I would be happy to provide that.

[The information can be found in the appendix.]

Mr. MICA. I wrote the Secretary regarding your conduct on September 22, 1993, relating to the citing of an Agricultural Research Service Center and I still haven't received the courtesy of a response from the Secretary. Can you ask the Secretary when that will be forthcoming?

Mr. ROMINGER. Yes, I certainly will. I saw that correspondence and I signed off on the reply, so I don't know what has happened.

Mr. MICA. I may only be here for 13 or 14 more months, but as long as I am here, I expect truthful conduct from you and from that Department, or I will be on your case like you couldn't imagine, so I appreciate your compliance. And I just want to make that statement today for the record, and I expect that information by the 15th.

Dr. Goldman, the pesticide that I mentioned earlier is micromite. It is currently in use in California and Texas. It is used for gypsy moths and mosquito control. Can you provide for me a written response to the status of that product as it relates to use in Florida?

Dr. GOLDMAN. I certainly can.

Mr. MICA. I would like an update on that as soon as possible.

[The information can be found in the appendix.]

Mr. MICA. It is my understanding also, Dr. Goldman, that the administration's food safety proposal would authorize citizen suits against farmers for alleged violations of FIFRA. Aren't you concerned that allowing these private suits against farmers would foster expensive litigation as well as disrupt the agricultural projection process?

Dr. GOLDMAN. Our overall experience in the EPA with citizen suits provisions, has been that there have been very few abuses of them. It has not created enormous legal burdens either for the other industries involved or for the EPA.

Mr. MICA. Does it enhance pesticide safety, this process? Is it worthwhile?

Dr. GOLDMAN. The agency believes that the ability for a citizen to file a suit, to ensure that the agency is enforcing the law that it is supposed to enforce, is an important check or a safeguard on government.

I think it is important to understand that these suits are filed to ensure that the agency is just enforcing the law.

Mr. MICA. But it is going to be your policy to promote this?

Dr. GOLDMAN. Yes.

Mr. MICA. Let it continue?

Dr. GOLDMAN. We have those kinds of provisions in most environmental statutes. We are quite comfortable with those provisions.

Mr. MICA. It is my understanding that the administration's proposal does not contain a tolerance uniformity provision; is that correct?

Dr. GOLDMAN. We did not include a provision like that in our package. I think that is an area that we would like to work with Congress on.

Mr. MICA. I would like to see the—see you all come back with something. How long do you think it would take to develop some recommendation there?

Dr. GOLDMAN. I actually believe that our commitment in that area is to work with the Congress on the——

Mr. MICA. No specific recommendation though?

Dr. GOLDMAN. Exactly.

Mr. MICA. You stated earlier that the individual that you deal with primarily at the White House was Katie. Was that correct, for policy? What about Vice President Gore? Have you dealt with him as the——

Dr. GOLDMAN. I personally have not dealt with Vice President Gore.

Mr. MICA. So the administrator is dealing with him. You are aware that one of the Vice President's National Performance Review recommendations endorses the President's Executive order to streamline the regulatory review process, and in doing so, to take into account the broad range of costs and benefits which will be more useful and realistic than our current regulatory practices?

You are aware that the Senate just passed what is referred to, I guess, as the Johnston amendment in the EPA elevation bill, of a vote 95 to 3, which today requires that rules promulgated by EPA are subject to a cost and comparative analysis. Is the agency supportive of that action?

Dr. GOLDMAN. I am not working on that issue but I believe that we are not. I think that what the agency is concerned about is, you know, what kind of actions can be interpreted as falling under that, and we don't want to place ourselves in an absurd position as the government often places itself, of requiring enormous analyses for actions that are too trivial to deserve them.

Mr. MICA. You have been in this field for a while and you have seen what is happening. You are aware of the testimony here today in the little area of pesticides. Don't you think some cost-risk-benefit analysis should be a part of your priorities too as an agency?

Dr. GOLDMAN. I think that it definitely should be a part of our priorities. I will tell you, within the pesticide program that issue is always a consideration and in decisions under FIFRA, and in fact we have an entire division that does nothing but assess the benefits and to help weigh those considerations.

So it is not really a philosophical disagreement about whether you should ever look at that. It is just a question of, is it necessary to perform a separate study of that for every single decision and rule.

Mr. MICA. You are one of the highest administrators in EPA, and you are new to the job, and I welcome you. I know you are going to try to do your best, but you have heard some of what the problems are with my little company and a little area of pesticides. I serve on a subcommittee of this—another subcommittee, which is Human Resources and Intergovernmental Relations. We have been conducting hearings on Federal mandates, and let me share with you, if I may, just for a second what I am hearing.

I was in the Capital of Pennsylvania, Harrisburg, for a hearing on Monday of this week, and local governments are absolutely beside themselves with what you all have done. The biggest complaint I hear about Federal mandates is EPA.

You brought up clean air and water, a few minutes ago. Let me tell you, these people are at their wits end. They have raised their sources of revenue, which are property taxes, for compliance—again, it is all this risk-benefit analysis. The mayor of one city told me 80 percent of his budget is mandated. They told me that in order to comply with EPA's clean water requirements, that it could very well bankrupt their community. They are at their millage caps. They have millage caps. They are not like we are. We can tax people and tax people, which we are doing, but they have some limits.

So these people are really beside themselves as to compliance. I could get you files from the people in my district where they have now come in for water testing and other things; small businesses, a dry cleaner has spent $25,000 in surveys and testing for a well that had been there for years. This community told me it would be cheaper to deliver bottled water to the community than to comply with what you are talking about.

So let me tell you that the local governments are hanging on by a hair, frankly, and that there has to be some reason to all this. Your job is in fact to protect the safety and health and welfare of the public—an admirable task, which I support—but we have got to look at this in some reasonable fashion. So with that, I will just give you the message that I have been getting from those hearings and ask for your assistance as we move forward.

Mr. SYNAR. Thank you, Mr. Mica.

Dr. Goldman, let's get back to you.

The GAO report cites a few very particular and very disturbing findings. One of them is the rejection rate for studies submitted by pesticide companies. For some kinds of studies, that rejection rate is as high as 45 percent. What are you doing about that rejection rate?

Dr. GOLDMAN. Well, the pesticide program, prior to my arrival on the scene, had already, in response to that GAO report, begun a series of rejection rate studies and I think all but one of those studies is now complete. And what the studies were about were to identify the reasons why studies were being rejected. And I think that one of the main conclusions was that, in many areas, the guidance that was given to the registrants was not specific enough to assure that they actually knew what was required.

Mr. SYNAR. So right now, based upon this, there is no excuse for any more delays because you have cleaned up the vagueness and misunderstanding?

Dr. GOLDMAN. We think once the misunderstandings are cleaned up, then there isn't an excuse for these rejections and delays created by them.

I think another thing that we have to do is that, given that we are in this situation, we need to retain the commitment in the agency to not wait until all the studies about a particular chemical are in to start reviewing them, but rather to try as much as possible to review information as it comes in and to start addressing risks as they are brought to our attention.

Mr. SYNAR. In the past, because your guidance was so vague and there were so many misunderstandings, you were unwilling to take a product off the market during the "redo," as we call it.

Dr. GOLDMAN. That is true.

Mr. SYNAR. Now, are you confident enough that you will actually suspend a registration if the data is late or not acceptable.

Dr. GOLDMAN. I am.

Mr. MICA. Mr. Chairman, I am going to have to leave, but I would like unanimous consent that the record be left open for whatever is appropriate for submission of additional questions.

Mr. SYNAR. We will also enter Mr. Sanders opening statement and any other opening statements under that request.

[The prepared statement of Mr. Sanders can be found in the appendix.]

Mr. MICA. Thank you, Mr. Chairman.

Mr. SYNAR. Another fear, Dr. Goldman, we have, is that over 3,000 unreviewed list "A" studies might include some which will be rejected, and if it is a key study, then that review for that pesticide will have to be delayed until a new study is completed. If you are confident about the guidelines now, is it possible to include a self-appraisal of those unreviewed studies by the registrant as a 6(a)2 requirement?

Dr. GOLDMAN. I am not sure about that. That is something I am going to have to look into.

Mr. SYNAR. Another recurrent theme in almost every GAO report about pesticides is the lack of a management strategy. How long will you need to develop a strategy plan?

Dr. GOLDMAN. I actually believe that there is a plan.

Mr. SYNAR. I want a deadline of when we get a plan that is workable. When do you think it will be ready? Do you think it is ready right now?

Dr. GOLDMAN. I believe that we do have a workable plan right now. Maybe what we need to do is find a way to share that plan with you so that we can interact more effectively.

Mr. SYNAR. Very candidly, since you are new, let me give you the history of this. Every strategy plan that we have seen has had to be reconfigured every 3 years, and then for 18 months we have been told that a new plan is in place. Then for 12 months, we have been told a new plan is being formulated, leaving 6 months of accountability for any particular plan. We are starting to notice that same pattern, by the way, in the toxics program, a situation which we will address at another hearing.

My point is that if you need amendments, then let us enact them. But we have got to get on this thing to where we can get this in motion. Do we have your commitment to that?

Dr. GOLDMAN. You do.

Mr. SYNAR. Let me conclude today's hearing by again welcoming you both to the wonderful world of congressional oversight. We take our responsibility very seriously and for any of those who are in the audience who doubted that this subcommittee would be any less active in this area during a Democratic administration than a Republican administration, I think you can see by our remarks today that we have now set marks that we will come back to and by which we will judge both USDA and EPA. This is a subject which I hope, that within the next two sessions of Congress, we can put behind us and have a program that is running.

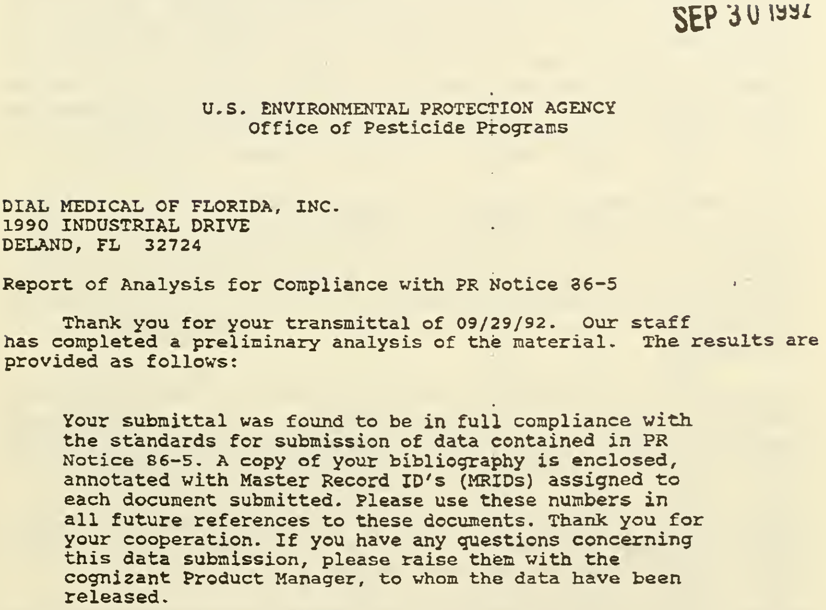
Dr. Goldman, I will conclude with something I think is very important, which is that we welcome you to this. We appreciate your sincerity and dedication. We want to work with you on this, but we want you to know that it is critically important that we finally resolve the problems which have existed for over a decade.

And with that, this subcommittee is adjourned.

[Whereupon, at 12:05 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD



SEP 30 1992

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

DIAL MEDICAL OF FLORIDA, INC.
1990 INDUSTRIAL DRIVE
DELAND, FL 32724

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/29/92. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

> Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

IPM ADOPTION IN U.S. AGRICULTURE

IPM is a management process and does not rely on a defined set of tactics. While the principles of IPM are generic, the tactics that make up an IPM program are crop and region specific. As such, universal standards for defining IPM adoption, beyond the basic principles of scouting and the use of economic thresholds, are impossible to establish. Until crop-specific, regional guidelines are developed, the measurement of IPM adoption by growers is problematic. At this point we can only measure adoption based on the use of scouting and thresholds.

The 1989 National Academy of Sciences' report, Alternative Agriculture, presented IPM adoption data for 12 crops based on various surveys taken during 1986. Adoption in this report was based on the use of both scouting and economic thresholds. Pooling the data on all 12 crops gives an average of 23% adoption, ranging from only 4.7% on alfalfa to 82% on tomatoes. Specialty crops used scouting and thresholds on well over 50% of the acreage. Field and forage crops, which have a lower value and cannot support expensive consulting costs, used scouting and thresholds on less than 50% of the acreage, ranging from 4.7% to 39%. The larger acreage of these crops tends to bias the overall crop average downward.

As part of the Pesticide Data Program, the National Agricultural Statistics Service began surveying producers in 1991 on various production practices including adoption of IPM. The 1991 survey covered 29 fruit and nut crops in 13 states and the 1992 survey covered 20 vegetable crops in 14 states. The surveys involved interviews with individual producers and were designed to be statistically representative of 70% to 100% of U.S. producers for each crop. The Economic Research Service is analyzing the data, but some preliminary results can be provided.

The 1991 study showed that scouting was practiced on 50% or more of the surveyed acreage of major fruit and nut crops, including apples (54%), grapes (68%), pears (59%), oranges (75%), almonds (64%), and walnuts (65%). Typically, the results of these scouting efforts were used for decisions on pesticide applications on 75% or more of the scouted acreage.

The 1992 study showed that scouting was practiced by about 60% of the surveyed vegetable producers. Economic thresholds were employed in the application decisions for 52% of insecticides, 35% of fungicides, and 39% of herbicides.

As part of the 1992/1993 Objective Yield Survey, NASS also surveyed producers of corn, soybeans, and potatoes on their pest management strategies. The survey of corn producers, statistically representing 54 million acres in 10 states, showed that scouting was practiced on 64% of corn fields and that economic thresholds were used for 53% of the herbicide applications and 42% of the insecticide applications. Soybean producers, representing 41 million acres and 8 states, scouted 69% of their fields and used economic thresholds on 60% of their herbicide applications. Potato producers, representing 544,000 acres in 4 states, scouted 92% of their acreage and used thresholds for 69% of their herbicide applications, 44% of their insecticide applications, and 40% of their fungicide applications.

UNITED STATES DEPARTMENT OF AGRICULTURE
SELECTED PESTICIDE RELATED PROGRAMS
(Dollars in Thousands)

27-Oct-93

	1992 Actual	1993 Estimate	1994 Current Estimate	Federal FTE
PESTICIDE RECORDKEEPING:				
Agricultural Marketing Service......	0	1,500	1,511	9
NATIONAL AGRICULTURAL PESTICIDE IMPACT ASSESSMENT PROGRAM:				
Agricultural Research Service.......	860	860	871	6
Cooperative State Research Service..	2,968	2,968	1,568	2
Extension Service..................	3,405	3,405	3,363	3
Economic Research Service..........	400	400	300	2
Forest Service.....................	361	361	361	0
Subtotal, Natl. Ag. Pest. Impact..	10,962	10,962	8,031	
PESTICIDE APPLICATOR TRAINING:				
Extension Service:				
EPA Pass-through..................	1,680	1,680	1,680	1
Subtotal, Pest. Applicator........	1,680	1,680	1,680	
TOTAL:				
Agricultural Marketing Service....	11,862	13,058	13,102	35
Agricultural Research Service.....	58,584	58,389	60,627	921
Agricultural Stab. & Conserv. Serv	2,900	5,505	10,472	a/
Animal & Plant Health Insptn. Serv	11,659	12,499	13,916	228
Cooperative State Research Service	39,498	39,447	42,747	0
Economic Research Service.........	3,050	3,050	2,950	10
Extension Service.................	13,285	13,285	13,502	4
Forest Service....................	18,418	12,538	12,427	97
Human Nutrition Information Ser...	7,000	5,038	8,600	67
Natl. Agricultural Statistics Ser.	3,497	3,600	3,600	56
Total, USDA, Sel. Pesticide Progs.	310,956	311,395	325,349	

a/ Program managed as part of total conservation cost-share effort through county offices. No Federal ASCS staff specifically dedicated to IPM.

b/ Included in totals for research under Integrated Pest Management.

NOTE: CSRS and ES programs provide grants to support programs at the State and local levels. FTE levels shown are for Federal program management.

UNITED STATES DEPARTMENT OF AGRICULTURE 27-Oct-93
SELECTED PESTICIDE RELATED PROGRAMS
(Dollars in Thousands)

	1992 Actual	1993 Estimate	1994 Current Estimate	Federal FTE
IR-4 PESTICIDE CLEARANCE:				
Agricultural Research Service	$2,133	$2,142	$2,142	11
Cooperative State Research Service	4,420	4,446	7,889	1
Subtotal, IR-4 Pest. Clearance	6,553	6,588	10,031	
INTEGRATED PEST MANAGEMENT:				
Research:				
Agricultural Research Service	10,237	11,053	11,698	174
Cooperative State Research Service	24,286	24,250	23,750	3
Economic Research Service	200	200	200	1
Forest Service	10,158	10,177	10,177	95
Subtotal, Research	44,881	45,680	45,825	
Control:				
Agricultural Stab. & Conserv. Serv.	2,900	5,505	10,472	a/
Animal & Plant Health Insptn. Serv.	4,122	2,500	2,300	55
Forest Service	7,899	2,000	1,889	2
Subtotal, Control	14,921	10,005	14,661	
Education:				
Extension Service	8,200	8,200	8,459	1
Subtotal, Int. Pest Management	68,002	63,885	68,945	
BIOLOGICAL CONTROLS:				
Research:				
Agricultural Research Service	45,354	44,334	45,916	730
Cooperative State Research Service	7,824	7,783	9,540	1
Economic Research Service	50	50	50	0
Forest Service b/	(3,225)	(3,725)	(3,375)	b/
Subtotal, Biol. Controls Research	53,228	52,167	55,506	
Control:				
Animal & Plant Health Insptn. Serv.	7,537	9,999	11,616	173
Subtotal, Biological Controls	60,765	62,166	67,122	
PESTICIDE DATA COLLECTION:				
AMS - PDP Residue Surveys	11,862	11,558	11,591	26
ERS Survey Data Analysis	500	500	900	7
ERS Pesticide Use Surveys	1,900	1,900	1,500	0
NASS Pesticide Use Surveys	3,497	3,600	3,600	56
HNIS Food Intake Surveys	7,000	5,038	8,600	67
Subtotal, Pesticide Data Coll	24,759	22,596	26,191	

THE DEPUTY SECRETARY OF AGRICULTURE
WASHINGTON, D.C.
20250-0100

November 16, 1993

The Honorable John L. Mica
U. S. House of Representatives
427 Cannon House Office Building
Washington, D. C. 20515-0907

Dear Congressman Mica:

I regret that we have not been able to visit in the past few weeks. As you know, I tried to reach you by telephone on November 5th and again this morning to discuss your concerns about the decision to relocate the Agricultural Research Service laboratory at Orlando to Fort Pierce, Florida. Some insight into the resolution of this matter from the Department's standpoint may be helpful in explaining this situation. This also responds to your letter of September 22 to Secretary Espy.

When we took office in January, the Department inherited a decision by former Secretary Madigan to relocate this facility to Fort Pierce. Secretary Madigan's site selection and review team included representatives from both USDA and the Florida citrus and vegetable industries. After a lengthy review process, Secretary Madigan was advised that the two best possible sites in Florida were at Fort Pierce and Immokalee. Ultimately, Secretary Madigan selected the Fort Pierce site.

Secretary Espy was asked to take a hard look at the decision and to resolve the matter as quickly as possible. I was asked by the Secretary to lead this effort. Thus, the matter was under review during the spring as the Congress proceeded with the appropriations process. During the June 29, 1993 debate in the House on the Department's fiscal year 1994 appropriations bill, Congressman Porter Goss raised concerns about the location of the facility. In response, Chairman Richard Durbin agreed to schedule a meeting with appropriate Departmental officials to provide an opportunity for a fair hearing on the issues.

Consistent with this commitment, a meeting with the Florida House Congressional delegation was called by Chairman Durbin on August 5, 1993. At this meeting, which was attended by me and others from the Department, a case was made for reversing the decision of Secretary Madigan in order to locate the laboratory at Immokalee. A case was also made in support of Secretary Madigan's decision to relocate the laboratory to Fort Pierce. Notwithstanding the discussion, and disagreement among the Members and industry representatives about the two sites, it was urged by all in attendance that the Department make its decision quickly in order to put the matter to rest. I reported to the Secretary and was instructed by him to handle this matter directly and to make a recommendation as soon as possible. I did so and plans were made to make the decision public.

When you requested the September 9 meeting, I decided to hold our decision for reconsideration based on the outcome of the meeting. Unfortunately, due to a death in my family, I was unable to attend the meeting. Previously I had planned to attend your meeting and leave Washington on the afternoon of September 9th. However, please know that your participation in this meeting was real. The Secretary's hope all along has been that the delegation and the interested parties in Florida could mutually agree on a site for the relocation of the laboratory.

Unfortunately, no such consensus was expressed at the September 9th meeting. In fact, two new and different proposals were discussed, including one for the reconstruction of the current facility and another for the location of the facility at a third site. A telephone discussion with me was held following the meeting where it was decided that neither of the new proposals was sufficiently developed to change our decision regarding the Fort Pierce selection. Only at the conclusion of this discussion were the letters which had been prepared, signed, and dated prior to my planned departure sent out.

When Dr. Plowman and my executive assistant returned from the September 9th meeting with you they learned that the Secretary, not knowing that we had delayed a decision pending the meeting with you, had talked with Congressman Hastings and mentioned that we had been planning to reconfirm the decision to relocate the laboratory to Fort Pierce.

I sincerely regret the chain of circumstances, but must reiterate that the meeting of Dr. Plowman and my executive assistant with you was held in good faith and information from that meeting was carefully considered before we announced the decision. Needless to say, your suggestion at the public hearing on October 29th that I had lied to you has been a source of serious personal concern.

Enclosed per your request are pages from notes that I normally make to help me keep track of my work. I do not keep a detailed journal or diary. Because the notes mention names of individuals, I would request that you keep this information confidential. The entry for September 8 is for meetings in Washington, and there is a simple entry for September 9 through 20 which notes my travel to California and Nevada.

By way of further explanation, I departed Washington for California on the evening of September 8th. My activities on November 9th included serving as a pallbearer in the funeral for my cousin, after which I began a series of speaking engagements and business meetings ending with my return to Washington on September 20. During this period I met with the California Food and Agriculture Committee and other USDA employees, spoke with the editorial board of the San Francisco Chronicle, spoke at the opening of the Kern Agricultural Pavilion, addressed the 1993 Pacific Region Conference of Soil Conservation Districts in Minden, Nevada, met with members of the Agland Investment Service, and addressed the Solano County Breakfast Roundtable.

I remain available to meet with you if it would be helpful.

Sincerely,

Rich Rominger

RICHARD ROMINGER

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 2 1994

Honorable John L. Mica
House of Representatives
Washington, DC 20515

Dear Mr. Mica:

This letter follows-up to your questions raised at an October 29, 1993, Congressional hearing in which you inquired about the status of registration of the pesticide product, Micromite (active ingredient, diflubenzuron), as an insecticide for use on citrus crops in Florida. A number of other parties have also inquired about the registration of Micromite.

We have recently written to Mr. Bob Crawford, Commissioner, Florida Department of Agriculture and Consumer Services, who wrote to the Environmental Protection Agency concerning the registration of Micromite. I have enclosed a copy of the Agency's letter to Mr. Crawford which explains the issue surrounding the registration of Micromite.

I hope you find this information helpful. Please feel free to contact EPA again if we can be of further assistance.

Sincerely yours,

Lynn R. Goldman, M.D.
Assistant Administrator

Enclosure

OPP/PSPS: KTTHOMAS:308-3275:2/16/94
F:\USER\PSPS\LETS94\Mica.ktt No control
bcc: TS(2) AL REGION 4
Arty Williams (FOD/OPP), Phil Hutton (RD/OPP)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB - 8 1994

Mr. Bob Crawford, Commissioner
Florida Department of Agriculture &
Consumer Services
The Capitol
Tallahassee, FL 32399-0800

Dear Mr. Crawford:

The Integrated Pest Management (IPM) approach to controlling citrus pests is a very commendable effort to reduce the amount of pesticide used while obtaining acceptable control of all pests affecting the yield and quality of oranges and grapefruit. EPA encourages the development and registration of pest control agents which are less hazardous to people and other non-target organisms.

The pesticide product you mention in your October 28, 1993 letter (Micromite, alternate trade name Dimilin) contains an active ingredient by the name of diflubenzuron. Diflubenzuron has as a metabolite the carcinogenic substance, parachloroaniline (PCA). EPA is reviewing the available data to determine whether the anticancer provision, otherwise known as the Delaney clause, of section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits establishing food or feed additive regulations for diflubenzuron in/on citrus oil and pulp. If EPA cannot establish the food or feed additive regulations necessary for use of Dimilin on citrus crops, EPA's current policy is to deny the registration amendment.

Priority is being given to resolving the issues associated with the proposed use of products containing diflubenzuron on oranges and grapefruit.

Also, I should mention that Solvay Duphar B.V. (Solvay), the registrant of products containing diflubenzuron, requested that the Dimilin product label be amended to include the control of citrus rust mite on oranges and grapefruit. Solvay did not request that the Dimilin product label be amended to include the control of the West Indian Sugarcane Rootstalk Borer Weevil, *Diaprepes abbreviatus*, or the citrus leafminer, *Phyllocnistis citrella*. However, under section 2(ee) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), unless the Administrator has determined that the use of products containing diflubenzuron against pests other than those outlined on the product label would cause an unreasonable adverse effect on the environment, it is not a misuse to target a pest not specified on the label if the application is to the crop, animal, or site specified on the label.

Again, every effort will be made to resolve the issues in a timely manner.

Sincerely

Stephen L. Johnson, Acting Director
Registration Division

BERNARD SANDERS
MEMBER OF CONGRESS
VERMONT, AT LARGE

213 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4501
TELEPHONE 202-225-4116
FAX: 202-225-6790

Congress of the United States
House of Representatives
Washington, DC 20515-4501

COMMITTEES
BANKING, FINANCE AND URBAN AFFAIRS
GOVERNMENT OPERATIONS

1 CHURCH STREET, SECOND FLOOR
BURLINGTON, VT 05401-4417
TELEPHONE 802-862-0697
TOLL FREE 800-339-9834
FAX 802-860-6370

October 29, 1993

Statement for the Subcommittee on Environment, Energy and Natural Resources' Hearing -- Food Safety Reform: Still Trying After All These Years
Representative Bernard Sanders

Let me begin by thanking the Chairman for his strong and continued concern over the EPA's inability to adequately meet deadlines on pesticide registration and what that means for public health in this country. This year the Chairman and I have had a good deal of experience with the EPA's sluggishness in dealing with the toxic substances associated with carpets.

In the mid 1980's a virtual "health emergency" struck the EPA itself. Thousands of employees, 40 percent of the workers, at the EPA headquarters came down with illnesses related to the indoor environment at the EPA. Employees collapsed at work and were rushed to the hospital and the building was evacuated a number of times. The EPA's response to this situation was unacceptable. No study was conducted to determine the health effects of this exposure on employees. Instead, employees were harrassed and the EPA failed to cooperate with the employees' union. Based on the EPA's own legacy and disregard for employees and for the public in general regarding toxic carpets and indoor air quality, it does not surprise me that we are here today to discuss a failure to secure public health with relation to pesticides.

Today millions of Americans, and our precious environment, are exposed to many pesticides that have not been fully evaluated for their potential to cause cancer, reproductive disorders, birth defects, and environmental damage. In fact 15,000 products containing the the worst pesticides remain on the market, while knowledge of their health and environmental effects is incomplete. To me, this doesn't make any sense. Why don't we consider the human health effects of chemicals important enough to limit, suspend and prevent the use of these pesticides that have the greatest potential for human risk? While safety questions about certain pesticides have taken almost 20 years to resolve, the process of removing a registration from use can take 3 to 7 years. There are close to 20,000 pesticide products that still await reregistration. Let's face it, if we wait around for EPA reregistration of these pesticides, many of us won't be around to hear the results. Cancer or old age will have gotten us first.

The system is designed to favor the pesticide companies, not human health or farmers. Even the Special Review process, which is supposed to more quickly resolve safety questions, is designed to help the pesticide company, not the consumer. If there is evidence from laboratory tests that the pesticide might present an unreasonable risk of cancer, or present high risks to workers, the pesticide company must rebut the presumption that the risk is unreasonable. This scenario may make sense from an economic standpoint, but not from the perspective of human health. Once information is presented to rebut the evidence that the product should be cancelled, the product is allowed to return to the market. And the Special Review process might be a bigger problem than it is, if it were ever used. According to the Inspector General's report, "for the past four years, OPP has not started the regulatory special review process for any pesticides. Instead, OPP has used negotiations with pesticide registrants to achieve risk reduction." And these negotiations take place without the public involved in the decision making process. So now we must trust the pesticide companies to mitigate the risk voluntarily.

While all of this foot dragging continues, we have serious public health problems to deal with. Since the recent release of the National Academy of Sciences report on children and pesticides, we now know that the current system does not adequately protect infants and children from the possible risks of pesticides; the exposure data used by the EPA for risk assessment is poor; and the cancer risk to children is 2-4 times greater than estimated, using current EPA risk assessments assumptions. In addition, more and more studies are pointing to the connection between breast cancer and pesticides.

The improved health of our population depends on ending the delay in reregistration of pesticides, removing the worst pesticides from the market, and transforming our production of food to focus on sustainable agriculture. As the NAS study on children finally recognized, health cannot take the backseat to economic gain. I hope this hearing will be one in a series to refocus our priorities in this area, and I again thank the Chairman for his commitment to this issue.

J. DENNIS HASTERT
14th District, Illinois

2453 Rayburn House Office Building
Washington, DC 20515-1314
(202) 225-2976

27 North River Street
Batavia IL 60510
(708) 406-1114

1007 Main Street
Mendota IL 61342
(815) 538-3322

Congreſs of the United States
House of Repreſentatives
Waſhington, DC 20515-1314

COMMITTEE ON
ENERGY AND COMMERCE

COMMITTEE ON GOVERNMENT
OPERATIONS

EXECUTIVE COMMITTEE ON
COMMITTEES

SELECT COMMITTEE ON
HUNGER

The Honorable J. Dennis Hastert
Ranking Member
Environment, Energy and Natural Resources Subcommittee
Government Operations Committee
October 29, 1993

Mr. Chairman:

Among the many issues that the 103d Congress will address, pesticide safety reform is one of the most important as it will effect every man, woman and child in our country. The United States currently has the safest, most abundant and most affordable food supply in the world and it is imperative that we maintain this standard.

EPA Administrator Browner recently testified before Congress about the Administration's pesticide safety reform package. While the Administration and I agree on the goal of maintaining and enhancing food safety for all Americans, our methods of achieving this goal differ. I encourage the Administration to take a hard look at the "Food Quality Protection Act of 1993", more commonly referred to as the Lehman-Bliley-Rowland bill (H.R. 1627). This legislation has broad bi-partisan support, including myself as well as many members of this subcommittee. It is a reasonable and comprehensive approach for pesticide safety reform.

Of particular significance, the Lehman-Bliley-Rowland proposal

PRINTED ON RECYCLED PAPER

recognizes that children eat fruits and vegetables in greater abundance than adults and the effects of this additional intake need special consideration. Accordingly, this proposal allows EPA to build on evolving science rather than dictating to them how to define a children's standard. This provides the agency with the flexibility to make ongoing improvements in our protection of children as more is learned about this issue.

Another issue effecting pesticide safety reform is the Delaney clause. As we are all aware, in July of 1992, a federal appellate court struck down EPA's "de minimis" interpretation of the Delaney clause. The effect of this decision casts doubt on the continued use of many safe and effective pesticide chemicals. In February of this year, EPA identified a list of 32 pesticides used on 29 crops that could, under current policies, be lost as a result of the court's decision. In releasing this list, Administrator Browner carefully noted that "EPA does not believe that the pesticides in the following lists pose an unreasonable risk to public health, based on available data." Many of these pesticides are extremely important to the production of a variety of crops including citrus, tomatoes, apples, grapes, sugarcane and rice. Thus, it is important that EPA make every effort to implement Les v. Reilly in a responsible manner to minimize the potentially adverse consequences of the Delaney clause while maintaining a safe food supply for consumers.

I understand that a petition has been submitted to EPA that suggests that EPA can administratively implement the court's ruling on the Delaney clause. I look forward to hearing from EPA about the status of this petition.

Let me conclude by stating that reforming our pesticide laws is a complex and difficult task. Yet, Congress has the responsibility to ensure that our nation's food supply is safe. I look forward to working with the members on this subcommittee and those present today as we address this issue in the days and weeks that follow.

RELATED GAO PRODUCTS, 1986-1993

Pesticides: Issues Concerning Pesticides Used in the Great Lakes Watershed (GAO/RCED-93-128), Jun. 14, 1993).

The federal government and private organizations collect information on the amount of pesticides used in the United States, but no data systems exist that track pesticide usage in the United States. GAO estimates that each year at least 56 million pounds of pesticides from U.S. and Canadian sources end up in the Great Lakes watershed, including about 46 million pounds used on crops, eight million pounds used on lawns, and more than two million pounds used on golf courses. Pesticides that are repeatedly applied during the year on fruits and vegetables enter the Great Lakes and stay there, becoming more concentrated with time. The long retention time allows some pesticides to settle in lake-bottom sediments and become absorbed into the food chain. High levels of banned pesticides are still showing up in fish tissue. Preliminary findings by the Environmental Protection Agency (EPA) show that the effects of nine herbicides in current use may be more long lasting than once thought. EPA needs to complete its water quality monitoring program and use this up-to-date data in its reregistration program, which requires these pesticides to be reevaluated for their health and environmental effects. Data also indicate that millions of pounds of unusable pesticides being stored on farms present a disposal problem for the Great Lakes region. EPA has begun a program in the area to dispose of some of these pesticides, but large quantities remain, including banned, spoiled, and unneeded materials.

Pesticides: Status of FDA's Efforts to Improve Import Monitoring and Enforcement (GAO/T-RCED-93-55, Jun. 16, 1993).

Consumers rely on the Food and Drug Administration (FDA) to test imported and domestic crops for prohibited pesticides. Yet FDA has once again failed to meet some important milestones in developing the Import Support and Information System, which is intended to replace FDA's cumbersome manual processes and enhance the ability of FDA inspectors to stop imported foods adulterated with illegal pesticide residues from reaching U.S. grocery shelves. FDA has no idea when the system will be finished. GAO reported in September 1992 (GAO/RCED-92-205) that in four FDA districts about a third of the imported food in which FDA detected prohibited pesticides was not returned by importers to the Customs Service for supervised destruction or export. GAO continues to believes that FDA needs the authority to impose civil administrative penalties on importers who illegally distribute adulterated food shipments. FDA could also use its resources more effectively if it allowed its district offices greater discretion in placing growers and their imported foods on automatic detention status.

Pesticides: Pesticide Reregistration May Not Be Completed Until 2006. (GAO/RCED-93-94), May 21, 1993).

Many pesticides are in use today that have never been fully evaluated for their potential to cause cancer, reproductive disorders, birth defects, and environmental damage. More than 20 years ago, Congress required the Environmental Protection Agency (EPA) to reassess and reregister thousands of older pesticides using current scientific standards. Although EPA has made progress in completing the first several steps of the reregistration process, the agency will be unable to complete the pesticide reassessment in 1997 and product reregistration in 1998 as expected. EPA believes that the program may not be completed until 2006. Meanwhile, most of these products continue to be sold and distributed despite sketchy knowledge of their health and environmental effects. EPA will be unable to complete the program on schedule because it did not take into account the complexity and magnitude of the reregistration task or the resources needed to conduct the program. Also, a large number of the studies that the registrants submitted as part of the process have been unacceptable. In addition, EPA's progress in reregistering pesticides used mainly on food products--those with the greatest potential to cause serious health problems--has been much slower than expected. Concentrating on these high-priority pesticides could help EPA assess their risks more quickly and accelerate actions to reduce those risks.

Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects Are Uncertain (GAO/RCED-93-80), Apr. 6, 1993).

In their quest for perfect lawns, homeowners and lawn services are applying vast quantities of pesticides to eliminate weeds and insects. Yet the potentially dangerous consequences of these pesticides--from health and environmental problems to groundwater contamination--are not widely understood by the public. Although the Environmental Protection Agency (EPA) relies on reregistration to bring older pesticides into compliance with current scientific standards, the agency continues to fall behind its schedule to reregister pesticides. EPA's most recent estimates for obtaining required studies for 12 of the 18 major pesticides used in lawn care have slipped by as much as four years. Even after reregistration, the safety of lawn care pesticides is doubtful. EPA has not developed guidelines to assess the health effects of human exposure to pesticides after they are applied to lawns. In light of increasing reports of incidents involving pesticides, EPA is reconsidering its long-held view that pesticides pose no risk to the health of homeowners and their families. EPA is particularly concerned about the pesticides' effect on children, who may play on or around treated lawns. EPA has found 13 lawn care pesticides in groundwater and has identified four potential carcinogens among the 18 major lawn care pesticides.

Pesticides: U.S. and Mexican Fruit and Vegetable Pesticide Programs Differ (GAO/T-RCED-93-9), Feb. 18, 1993).

GAO testified that several differences exist in tolerances--maximum limits of pesticides allowed in or on foods--between the United States and Mexico. These differences fall into three main categories: (1) pesticides that have tolerances in both countries but have tolerance in Mexico for some commodities and no comparable tolerances in the Unites States; (2) pesticides that have tolerances in Mexico but none in the United States; and (3) pesticides that have tolerances in both countries for the same commodities, but at different levels. If Congress approves the North American Free Trade Agreement, the level of imported Mexican produce may soar. This anticipated rise has heightened concern among environmental groups that pesticide levels for Mexican produce may exceed U.S. limits if growers attempt to maximize production with the new opportunities for agricultural exports. Whether or not Congress approves the agreement, pesticide standards for produce will most likely play a larger role in trade discussions as imports from Mexico and other nations continue to increase. In addition, the Food and Drug Administration will need to continue monitoring fruits, vegetables, and other food imported into the United States from Mexico regardless of whether the agreement is enacted. GAO outlines several steps that need to be taken by both governments to ensure that Mexican produce does not violate U.S. pesticide tolerance levels.

Groundwater Protection: Validity and Feasibility of EPA's Differential Protection Strategy (GAO/PEMD-93-6, Dec. 9, 1992).

In surveying state officials across the country, GAO discovered that many states possess at least some of the data needed to assess the vulnerability of groundwater to pesticide contamination. Significant gaps in the data exist, however. Officials in only 15 states reported that data have been mapped in their state for all eight vulnerability factors necessary for doing valid assessments. Even when data are available, they often cover only part of the state and are not detailed enough to use in preparing valid assessments. In fact, no state has been completely mapped at a sufficient resolution for every factor. States need to collect more data if they are to conduct valid groundwater assessments. GAO found that the performance of vulnerability assessment models has been inconsistent. At best, existing models have been shown to predict groundwater vulnerability adequately only in some cases--that is, for some pesticides in some soils. Moreover, the model tests generally have not been done on the subcounty scale necessary to show whether the Environmental Protection Agency's differential strategy is either scientifically sound or economically viable. To be useful for regulatory purposes, both the models and their testing will have to be improved.

Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Food imports have tripled during the past 15 years; today, nearly half of the fresh fruits and vegetables eaten in the United States during the winter are imported. About four percent of imported produce tested by the Food and Drug Administration (FDA) during the 1980s contained banned pesticide residues, but some shipments were still distributed to grocery stores by importers who were not deterred by existing penalties. Although FDA told importers to return these shipments to the U.S. Customs Service for supervised export or destruction, about a third of the shipments were not returned in the four FDA districts GAO reviewed. Government records show that distribution of these foods by importers is a long-standing problem. Importers probably distribute adulterated foods because the consequences for doing so are slight; FDA rarely prosecutes and the damages assessed by Customs are low enough that importers can still make a profit. To spot more adulterated shipments with the same level of resources, FDA should: (1) ensure that shipments of the same food from the same grower arriving with sampled shipments are not distributed until the sample is determined to be free of prohibited pesticides, with a reasonable deadline for the test results to be given to Customs and the importer; and (2) delegate to the district offices greater responsibility to initiate automatic detention.

Sustainable Agriculture: Program Management Accomplishments and Opportunities (GAO/RCED-92-233), Sept. 16, 1992).

A combination of environmental and economic pressures caused by increased global competition and the escalating price of agrichemicals has spurred the federal government, farmers, and the agriculture industry to seek more globally competitive, profitable, and ecologically sound ways to produce food and fiber. This movement to alternative farming methods is called sustainable agriculture. Although the U.S. Department of Agriculture (USDA) has several programs to encourage sustainable agriculture, the responsibility for these programs is fragmented among various USDA officials, with no single entity overseeing and coordinating these activities. Because USDA lacks a policy that would provide direction on sustainable agriculture, program goals often conflict with one another and program coordination varies. In addition to discussing sustainable agriculture efforts in general, GAO specifically examines USDA's Sustainable Agriculture Research and Education Program and makes recommendations to improve these programs.

Pesticides: 30 Years Since Silent Spring--Many Long-standing Concerns Remain (GAO/T-RCED-92-77), Jul. 23, 1992).

GAO testified that many concerns about pesticides raised by Rachel Carson 30 years ago in her book Silent Spring and by more than 100 GAO reports over the past 24 years remain unresolved. The Environmental Protection Agency's pesticide reregistration program, for example, evaluates the health and environmental effects of older pesticides, but after 20 years, only two of more than 19,000 products have been reregistered. Other longstanding concerns discussed include difficulties in removing dangerous pesticides from the market, holes in the safety net designed to warn consumers of pesticide dangers, groundwater contamination, inadequate monitoring of pesticides in food, deficient notice to foreign governments about exported pesticides that are banned or unregistered in the United States, poor safety protection for farmworkers, and a lack of a coordinated federal strategy to manage key pesticide data.

Pesticides: Differences in U.S. and Mexican Pesticide Standards and Enforcement (GAO/T-RCED-92-62), Jul. 9, 1992).

GAO discussed U.S. and Mexican pesticide standards and enforcement of allowable pesticide residues on produce exported to the United States. GAO noted that: (1) the requirements for registering pesticides and setting tolerances are similar in the United States and Mexico; (2) 58 food-use pesticides have tolerances in Mexico and the United States, but have Mexican tolerances for some commodities without comparable U.S. tolerances; (3) there are 17 pesticides that have food-use tolerances in Mexico but none in the United States, and resolving those differences will be difficult since those pesticides have never been registered in the United States and the Environmental Protection Agency has never reviewed data for them; (4) Mexico and the United States have different processes for ensuring the safety of produce entering the United States; (5) the Food and Drug Administration has a sampling program to monitor imports and a special program to test Mexican produce for pesticide residues, while the Mexican government generally has limited capabilities in monitoring the safety of exported produce; and (6) from fiscal year (FY) 1988 through FY 1991, few DDT violations have appeared in the Mexican produce sampling primarily because potential adverse health and environmental effects have reduced or eliminated DDT use in Mexico.

Pesticides: USDA's Research to Support Registration of Pesticides for Minor Crops (GAO/RCED-92-190BR), Jun. 22, 1992).

Minor crops, including fruits, nuts, and ornamentals, accounted for more than 40 percent of the $30 billion in U.S. agricultural crop sales in 1990. Pesticides used to protect minor crops against insects and diseases have come under increasing scrutiny, and those registered before November 1984 must be reregistered with the Environmental Protection Agency by 1997 to ensure that they meet current health and environmental standards. The U.S. Department of Agriculture (USDA) is assisting with the reregistration process for minor crops through its Interregional Research Project No. 4 (IR-4), which relies on data from government, industry, and state universities. This briefing report examines (1) the status of the research that IR-4 coordinates to support the registration and reregistration of pesticides used on minor crops, (2) how IR-4 makes use of its resources, and (3) steps USDA has taken to ensure the availability of pesticides for use of minor crops after 1997.

Pesticides: Comparison of U.S. and Mexican Pesticide Standards and Enforcement (GAO/RCED-92-140, Jun. 17, 1992).

This report provides information on (1) U.S. and Mexican requirements for pesticide registration and tolerances, (2) differences in U.S. and Mexican tolerances for produce exported to the United States, and (3) the methods the United States and Mexico use to ensure safe levels of pesticide residues on produce entering the United States from Mexico. Overall, GAO found that the requirements for registering pesticides and setting tolerances--the maximum level of pesticide residue allowed on foods--are similar in both countries, with one major exception. The Mexican commission that registers pesticides generally gives less intense scrutiny to pesticides that have already been registered in the United States or other developed countries. By contrast, the Environmental Protection Agency (EPA) always does its own reviews and does not rely on other countries' registrations. Several differences in tolerances exist between the United States and Mexico. Officials from both countries have formed a working group to resolve these differences. While GAO believes that this effort is important, it is concerned that it does not go far enough. New pesticides are constantly being developed that may create differences in tolerance levels between the two countries, but the working group has no plans to address this issue. GAO recommends that EPA work with Mexican officials to resolve all types of pesticide differences. This strategy should also provide a long-term framework for the countries to deal with the constantly changing universe of pesticides.

Summary Information on Farmworkers (GAO/HRD-92-30R, April 10, 1992).

Pursuant to a congressional request, GAO summarized its recent reports and testimonies related to migrant and seasonal farmworkers. GAO noted that: (1) federal programs that serve the general population or workers in general do not provide assistance to many farmworkers; (2) due to limited funds, federal programs that primarily serve farmworkers can not provide assistance to all eligible farmworkers; (3) federal regulation of pesticides, workplace conditions, and child labor do not adequately protect farmworkers' health and well-being; (4) data on farmworkers are limited; (5) the supply of adequate farmworker housing falls far short of demand; and (6) agricultural employers frequently fail to pay wages for all hours worked, pay wages promptly, and pay minimum wage rates.

Pesticides: USDA's Pesticides Residue Research Project, (GAO/T-RCED-92-38, Mar. 11, 1992).

GAO discussed the Department of Agriculture's (USDA) role in the registration of pesticides for use on minor crops, focusing on: (1) the status of the USDA Interregional Research Project No. 4 (IR-4), which supports the Environmental Protection Agency's (EPA) pesticide registration process for minor crops; (2) how IR-4 uses its resources; and (3) USDA responses to the availability of pesticides for use on minor crops. GAO noted that: (1) EPA is required by the Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA) to reassess and approve, by 1997, pesticides registered before November 1984; (2) IR-4 will not complete the research necessary to support the registration of many high-priority pesticides for use on minor crops by the 1997 FIFRA deadline primarily due to funding limitations; (3) past and current IR-4 funding has not kept pace with the $12-million estimate, averaging only about $4.2 million annually since 1989; (4) IR-4 officials believe that they make effective use of limited resources, because they use the existing land grant university infrastructure, target the research agenda to include those pesticide uses that EPA is most likely to approve, and annually review research priorities; and (5) USDA has been slow to respond to the need for pesticides or minor crops, even though IR-4 officials developed a strategic plan in 1989 to address such concerns.

Food Safety: USDA's Data Program Not Supporting Critical Pesticide Decisions (GAO/T-IMTEC-92-9, Mar. 11, 1992).

GAO discussed the Department of Agriculture's (USDA) Pesticide Data Program, focusing on whether: (1) the program is producing the data needed to make improved pesticide regulatory decisions; and (2) USDA has a data management strategy to produce data resulting from the program. GAO noted that: (1) USDA established the program to collect pesticide usage and residue data that can be used to improve government decisions on pesticide safety within USDA, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA); (2) although USDA has made progress in collecting useful pesticide usage data, it lacks adequate residue collection procedures and reliable data on the quantity and types of pesticides applied on food crops; (3) USDA lacks an agencywide information resources management strategy critical to successfully collecting, processing, and disseminating pesticide data across the federal government; (4) the USDA pesticide usage surveys are proceeding on schedule, and EPA and FDA are generally satisfied with the published data; (5) problems that pose a significant risk to Pesticide Data Program success include a lack of specific written USDA agreements with EPA and FDA on program direction, a lack of a statistically defensible sampling plan capable of producing data equality based on the program's intended objectives, and USDA failure to determine adequate computer resources to process and disseminate the pesticide data; and (6) although GAO has made several recommendations to USDA to help establish a better program foundation, USDA does not agree with the recommendations, and has made little progress in implementing them.

Food Safety: Difficulties in Assessing Pesticide Risks and Benefits (GAO/T-RCED-92-33, Feb. 26, 1992).

GAO discussed federal regulation of pesticides, focusing on risk and benefit assessment of pesticides used in or on food. GAO noted that: (1) the Environmental Protection Agency (EPA), Food and Drug Administration, and Department of Agriculture share responsibility for regulating pesticide use for food, screening out those pesticides that present unreasonable risk, and approving those that provide benefits; (2) methodology and data limitations create uncertainties in the assessment of pesticide risks or benefits; (3) gaps in knowledge of pesticide risks and benefits contribute to the uncertainties; (4) EPA does not consistently acknowledge uncertainties inherent in its assessments; (5) federal food safety agencies lack a coordinated strategy for systematically identifying, collecting, and managing key data needed to reduce assessment uncertainties; (6) weak management of information resources and poor information system designs adversely affect data accessibility, reliability, and utility; (7) agencies do not always verify the accuracy and integrity of pesticide risk and benefit data; and (8) controversial policy issues hampering pesticide regulation include differing legal requirements, application of differing risk standards, and EPA inability to establish policy or guidelines in several areas of risk management.

Hired Farmworkers: Health and Well-Being at Risk (GAO/HRD-92-46, Feb. 14, 1992).

Pursuant to a congressional request, GAO provided information on the extent to which federal laws, regulations, and programs protect the health and well-being of hired farmworkers. FINDINGS: GAO found that: (1) federal laws and regulations do not ensure that hired farmworkers are given sufficient information about pesticide hazards; (2) according to Environmental Protection Agency (EPA) estimates, each year, hired farmworkers suffer up to 300,000 acute illnesses and injuries from exposure to pesticides; (3) EPA standards for protecting hired farmworkers exposed to pesticides do not require that they be informed on the specific chemicals they are exposed to or the potential health effects of those pesticides; (4) federal regulations on field sanitation do not protect hired farmworkers on small farms, and the Department of Labor's 1990 national survey of migrant farmworkers showed that 31 percent worked in fields without drinking water, handwashing facilities, or toilets; (5) federal labor law and child labor regulations allow children to work in agriculture at a younger age than in other industries; (6) children may be more susceptible than adults to the harmful effects of pesticides, and between 1979 and 1983, approximately 23,800 children and adolescents were injured on farms, 300 fatally; (7) most migrant farmworkers do not receive medical services from Medicaid or the Migrant Health Program because they are undocumented aliens or do not qualify for cash assistance programs; and (8) hired farmworkers are at greater risk than other workers to receive fewer Social Security benefits that they should, because their employers do not report all of their earnings to the Social Security Administration.

Food Safety: USDA Data Program Not Supporting Critical Pesticide Decisions (GAO/IMTEC-92-11, Jan. 31, 1992).

Pursuant to a congressional request, GAO reviewed the Department of Agriculture's (USDA) Coordinated Pesticide Data Program to determine whether: (1) the program produces the data needed for making improved pesticide regulatory decisions; and (2) USDA has an effective strategy for managing program data. FINDINGS: GAO found that: (1) USDA launched the Coordinated Pesticide Data Program to provide better pesticide data that would be beneficial to it, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) in their regulatory responsibilities; (2) the program's key objectives are to collect comprehensive, statistically valid, and scientifically based pesticide usage and residue data and to provide EPA with data it can use in making pesticide reregistration decisions; (3) USDA components plan to collect pesticide usage and residue data for fruit and vegetable crops from several states; (4) USDA pesticide usage surveys are proceeding on schedule, and EPA and FDA have expressed satisfaction with the resulting data; (5) USDA pesticide residue data collection efforts are behind schedule, have been significantly reduced in scope from original plans, and will not yield statistically reliable results; (6) USDA underestimated the complexities in planning and implementing activities and requirements for sampling methods, laboratory testing, and quality assurance; (7) USDA, EPA, and FDA lack an agreement as to program direction and assessment; and (8) USDA has not developed a strategy to determine whether available computer resources can adequately process or disseminate the data collected, and system requirements remain largely undefined.

Pesticide Monitoring: FDA's Automated Import Information System Is Incomplete (GAO/RCED-92-42, Dec. 31, 1991).

Pursuant to a congressional request, GAO reviewed the status of the Food and Drug Administration's (FDA) efforts to implement the Import Support and Information System (ISIS) to automate its import monitoring operations. FINDINGS: GAO found that: (1) ISIS development has taken FDA significantly longer than it originally estimated; (2) FDA did not meet system development and implementation milestones due to unrealistic projections and unexpected technical difficulties and procurement problems; (3) the ISIS core will provide FDA with a limited data base for reviewing and evaluating its import monitoring operations and ISIS data entry requirements will prevent the system from attaining the expected efficiency gains; (4) to fully achieve ISIS objectives, FDA is planning to implement an interface with the Customs Service's Automated Commercial System (ACS) to electronically link the two systems; (5) the ISIS-ACS interface will provide FDA with up-to-date information on the volume of imported products coming from various nations, allow ISIS to collect import data on most shipments of FDA-regulated products, and improve FDA program efficiency by substantially reducing the amount of time needed for FDA personnel to manually enter such data; (6) disagreements between FDA and Customs regarding system design have delayed the ISIS-ACS interface; and (7) although FDA plans to add screening and profiling modules to provide field personnel with additional data and guidance to improve their ability to identify violative products, it has not prepared detailed plans for developing and integrating them in the ISIS core.

Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessments (GAO/RCED-92-32, Dec. 31, 1992).

Pursuant to a congressional request, GAO evaluated the Environmental Protection Agency's (EPA) benefit assessments of pesticides used on food, focusing on: (1) EPA use of such assessments during special reviews of already registered pesticides; and (2) the extent to which EPA used adequate data, clarified limitations, and considered alternative pest-control measures. FINDINGS: GAO found that: (1) EPA primarily considers risk assessments in its reviews of already registered pesticides, and uses benefit assessments in a secondary role to help it to decide to cancel or restrict certain pesticide uses; (2) the quality of benefit assessments suffered because of poor, imprecise, or missing data, misleading analyses that do not acknowledge limitations, and incomplete analyses that do not consider promising pest-control alternatives; and (3) EPA could improve its benefits assessments by using more and better data on pesticide usage and comparative product performance, but EPA stated that it was difficult to obtain reliable data.

Groundwater Protection: Measurement of Relative Vulnerability to Pesticide Contamination (GAO/PEMD-92-8, Oct. 31, 1992).

Pursuant to a congressional request, GAO evaluated the feasibility of differentially protecting groundwater from pesticide contamination based on the relative vulnerability of different geographic areas, focusing on the degree to which: (1) states and counties are uniform in their susceptibility to groundwater contamination; and (2) two common measures of relative vulnerability diverge in identifying areas that are susceptible to contamination. FINDINGS: GAO found that: (1) although the Environmental Protection Agency (EPA) has taken the position that the variation in statewide sensitivity to pesticide contamination of groundwater is too large for uniform state-level management of pesticides, it has not taken a stand on how large the within-state areas to be managed differently should be; (2) since the variability in hydrogeologic vulnerability does not become significantly smaller when moving from the national level to the state and to the county levels, it generally makes no more sense to make distinctions between counties than it does to treat an entire state as a uniform area; (3) the lack of uniformity in vulnerability both between and within counties indicates that EPA risks undermining its differential protection philosophy if it permits states to differentially protect groundwater on the basis of county-level differences in vulnerability; (4) the system EPA endorses would target manifestly different areas for differential protection than a system that included data on population exposure; (5) techniques which provide valid vulnerability assessments at the subcounty level are expensive when applied across an entire county; and (6) it is important for states to explicitly consider the number of groundwater users as a factor in the development of differential pesticide management plans.

Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration (GAO/T-IMTEC-92-3, Oct. 30, 1991).

GAO discussed the Environmental Protection Agency's (EPA) information systems for ensuring that data submissions from firms reregistering pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act are properly identified, tracked, and reviewed. GAO noted that: (1) information on all data submissions made by registrants is repetitively entered and edited in several different information systems; (2) since information submitted by registrants may be scattered across nine different, non-integrated systems, EPA is unable to quickly compile a comprehensive and reliable picture of the review status of a particular pesticide; (3) manual records have to be compiled and verified, since critical information about pesticide studies is not kept in automated systems; (4) to fully integrate its information systems, EPA needs to establish standards for electronic data exchange and system interfaces, identify and eliminate data input and editing redundancies, and consolidate remaining individual systems; (5) tracking systems used by case review managers function as support for specific operations, rather than for management decisions, and make it difficult for EPA to respond to informational queries in a timely and effective manner; (6) current systems provide neither complete nor accessible information; and (7) rather than designing systems to provide timely and effective management support for a critical regulatory responsibility, EPA has narrowly focused on automating specific processes that simply track the movement of paper files.

Pesticides: EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed (GAO/T-RCED-92-16, Oct. 30, 1991).

GAO discussed the Environmental Protection Agency's (EPA) process for identifying, reviewing, and tracking required studies on the adverse health and environmental effects of pesticides, focusing on whether: (1) EPA knows the universe of studies it has received from registrants; and (2) recent EPA initiatives to improve the processing of those studies will ensure that it will timely identify and review all such studies. GAO noted that: (1) EPA may not have identified all unreasonable adverse effects studies that it received from registrants; (2) recent procedural changes will not ensure that all studies submitted to EPA will be reviewed; (3) the EPA tracking system will not provide the level of assurance EPA managers need to be confident that the job is being done right; (4) EPA does not have a uniform rule concerning a registrant's written statement that certain studies of long-term health effects, ecological effects, and pesticides' behavior in the environment do or do not meet or exceed any applicable criteria; (5) while registrants may have complied with section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act by submitting data on pesticides' unreasonable adverse effects, prior to 1988 EPA had no means of readily identifying all of the data as section 6(a)(2) submissions; and (6) the issuance of final regulations for implementing section 6(a)(2) to close the gaps that permit registrants to submit, but not specifically identify, unreasonable adverse effects data, would help ensure the timely identification and review of all such studies.

Lawn Care Pesticides: EPA Needs to Assess State Notification Programs (GAO/RCED-91-208, Sept. 25, 1991).

Pursuant to a congressional request, GAO provided information on the kind of notice the public receives when commercial applicators apply pesticides. FINDINGS: GAO found that: (1) state notification requirements vary in terms of who should be provided with information, when the information should be provided, what information should be provided, and whether the information must be requested; (2) 23 states require commercial applicators to provide notification when applying lawn care pesticides on residential sites, and as of April 1991, six additional states were considering requiring notification; (3) the primary notification methods include direct notification to customers, direct notification to neighbors upon request, and the posting of warning signs on treated lawns; (4) none of the 23 states that required notification had formally assessed the notification requirements' effectiveness; (5) EPA stated that they were aware of state notification programs, but lacked sufficient information to determine the programs' effectiveness; and (6) a lawn care industry trade organization supported states' efforts to require pesticide application notification.

International Food Safety: Comparison of U.S. and Codex Pesticide Standards (GAO/PEMD-91-22, Aug. 22, 1991).

Pursuant to a congressional request, GAO compared current U.S. and Codex Alimentarius Commission pesticide standards to determine the potential implications of such differences for U.S. trade and food safety. FINDINGS: GAO found that: (1) key areas where differences existed between the Codex and U.S. processes for establishing pesticide standards include the mix of pesticides included in each system, the use of good agricultural practices, pesticide and commodity definitions, data availability and interpretation, treatment of carcinogenic pesticides, and the use of dietary risk exposure assessments; (2) the Codex system includes about 170 pesticides and, when commodity groupings are converted to individual commodities, over 3,300 pesticide-by-commodity maximum residue limits (MRL), compared to over 400 pesticides and 8,500 pesticide-by-commodity MRL in the U.S. system; (3) MRL cannot be directly compared in about two-thirds of the Codex cases because the United States either has no standard or standards are defined differently; (4) less than half of the one-third of the pesticide-by-commodity combinations that can be compared are numerically the same; (5) among pesticides that the Environmental Protection Agency (EPA) rated as possible carcinogens, the U.S. had lower MRL in 55 percent of the cases; (6) differences between U.S. and Codex MRL for major U.S. agricultural exports and imports showed that the United States had lower MRL for about 20 percent and Codex for 37 percent of the pesticide-by-commodity combinations; (7) the potential for restrictions on exports and imports and greater consumer exposure to pesticide residues will remain as long as differences in pesticide standards exist; and (8) the United States needs to systematically review and assess existing pesticide-by-commodity standards to determine if harmonization improvements can occur.

Hazardous Materials: Chemical Spill in the Sacramento River (GAO/T-RCED-91-87, Jul. 31, 1991).

GAO discussed issues concerning the federal regulation of hazardous materials transportation and the circumstances surrounding a California train derailment that spilled 20,000 gallons of metam sodium, a weedkiller and pesticide, into the Sacramento River. GAO noted that: (1) the actual cause of the accident is still unknown; (2) neither the Environmental Protection Agency nor the Research and Special Programs Administration (RSPA) classify metam sodium as a hazardous substance, but the Coast Guard has designated metam sodium a hazardous material for liquid bulk transportation since it is highly toxic to marine life; (3) the Federal Railroad Administration's (FRA) inspection program was not effective, because it lacked inspection coverage standards, did not target railroad inspections based on accident and inspection data, had no mandatory inspection follow-up programs, and did not uniformly apply safety regulations throughout the industry; (4) the FRA enforcement program did not encourage compliance with safety regulations; (5) the FRA hazardous materials programs did not ensure that railroads and shippers followed RSPA regulations governing rail transportation of hazardous materials; and (6) RSPA and FRA initiated some actions to implement the Hazardous Materials Transportation Uniform Safety Act to achieve greater uniformity and consistency in the laws governing hazardous materials transportation, but lack of funds hindered their efforts.

Nutrition Monitoring: Mismanagement of Nutrition Survey Has Resulted in Questionable Data (GAO/RCED-91-117, Jul. 26, 1991).

Pursuant to a congressional request, GAO examined the Human Nutrition Information Service's (HNIS) 1987-88 Nationwide Food Consumption Survey (NFCS), focusing on the: (1) methodological soundness of the 1987-88 survey; and (2) effectiveness of the Department of Agriculture's management of the contractor hired to conduct the survey. GAO found that: (1) flaws in the methodology of the 1987-88 survey, deviations from the survey's original design, and lax collection and processing controls raised doubts about the quality of the data in the 1987-88 survey; (2) results from the survey were not representative of the U.S. population, since only 34 percent of the households in the basic sample provided individual intake data; (3) some households may have been discouraged by the length and complexity of the NFCS questionnaire and the absence of incentives to participate; (4) poor contract management contributed to cost overruns, delays, and the contractor's failure to complete certain contract tasks; (5) contract costs increased from $6.2 million to $7.6 million and contract completion was delayed by 2 years; (6) the contracting officer's representative frequently exceeded his authority by directing the contractor to forego certain contract requirements and undertake unspecified work, and the contracting officer did not monitor the contract; and (7) the contractor did not complete key procedures required by the contract, which violated internal controls designed to protect the government from fraud, waste, and abuse.

Pesticides: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse (GAO/T-RCED-91-83, Jul. 7, 1991).

GAO discussed the Environmental Protection Agency's (EPA) administration of the emergency-use exemption provision of the Federal Insecticide, Fungicide and Rodenticide Act, which allows states and federal agencies to use unregistered pesticides in an emergency without having to go through the EPA registration process. GAO noted that: (1) since 1978, EPA has granted over 4,000 specific and crisis unregistered pesticide exemptions; (2) in fiscal year 1990, EPA granted almost 80 percent of the exemption requests for chemicals that had already received exemptions for that particular use, and approved another 18 percent of the repeat requests by not revoking crisis exemptions; (3) by granting repeat exemptions, EPA may put companies that register pesticides at an economic disadvantage compared with companies that are able to sell their chemicals for unregistered usage; (4) since unregistered pesticides do not go through the EPA registration process, the extent of their effects on human health and the environment are unknown; and (5) the high number of repeat exemptions was due to a lack of criteria defining a complete registration application and nonspecific regulations precluding EPA from defining routine situations as emergencies.

Pesticides: Food Consumption Data of Little Value to Estimate Some Exposures (GAO/RCED-91-25, May 22, 1991).

Pursuant to a congressional request, GAO examined the reliability of the Environmental Protection Agency's (EPA) exposure estimates for safe pesticide levels and its reduced sample size, focusing on the adequacy of the Department of Agriculture's (USDA) 1987-88 food consumption survey data for EPA to estimate maximum dietary exposure to pesticide residues in food. FINDINGS: GAO found that: (1) budget constraints caused the reduction of the 1987-88 survey sample size by about one-third of the 30,770 individuals USDA surveyed in 1977-78; (2) survey limitations raised questions about its usefulness even for large subpopulations; (3) EPA did not participate in the 1987-88 survey's sampling design; (4) EPA's ability to adequately base tolerance assessments on exposure estimates for the five smallest subpopulations may have been compromised, since the sampling error for these groups ranged from nearly 70 percent to 175 percent of the estimate; (5) EPA did not determine precision levels for exposure estimates based on 1977-78 survey data; and (6) EPA based its tolerance decisions, in part, on exposure estimates that may have lacked the precision necessary for setting tolerances.

Pesticides: EPA and State Efforts to Ensure Safe Use of Lawn Care Pesticides (GAO/T-RCED-91-50, May 9, 1991).

GAO discussed the: (1) Environmental Protection Agency's (EPA) progress in reassessing the health risks of widely used lawn-care pesticides; and (2) notification policy the lawn-care industry extends to its customers and others regarding the commercial application of pesticides to residential lawns. GAO noted that: (1) approximately half the states required companies to provide some form of notification when applying pesticides to residential lawns; (2) lawn-care companies served nearly 12 percent of single-family households; (3) EPA did not require commercial firms to provide any type of public notification when treating residential lawns; (4) the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 required EPA to evaluate the risks and benefits of a proposed pesticide before it is registered for use and to reregister older pesticides to bring them into compliance with current data requirements and scientific standards; (5) the EPA reregistration process is falling behind schedule by about 32 percent; (6) the 17 states that provided for advance notification of customers and neighbors frequently placed the burden of obtaining such notification on customers; and (7) notification requirements, among states that have implemented notification programs, varied to a considerable degree in terms of whom should be provided information, when the information should be provided, and what information should be provided.

EPA Should Act Promptly to Minimize Contamination of Groundwater by Pesticides (GAO/T-RCED-91-46, May 8, 1991).

GAO discussed the Environmental Protection Agency's (EPA) efforts to minimize pesticide groundwater contamination, focusing on its: (1) assessment of pesticides' leaching potential; (2) regulation of pesticides that may leach into groundwater; and (3) consideration of human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food. GAO noted that: (1) EPA needed to take more initiative in ensuring the minimization of pesticide contamination; (2) EPA was slow in reviewing scientific assessments of pesticides' potential to leach into groundwater, resulting in the unavailability of detailed information concerning leaching factors to pesticide applicators; (3) EPA was slow in reassessing older pesticides; (4) while EPA sometimes used available regulatory measures, it could do more to help prevent further groundwater contamination; (5) EPA assessment of pesticide-contaminated food risks did not routinely consider additional exposure that could result from pesticide-contaminated groundwater, resulting in a lack of assurance that EPA set pesticide tolerances low enough to protect public health; and (6)

EPA planned to implement a new program assigning states a major role in managing pesticide use to minimize groundwater contamination, but EPA will still have to continue regulatory actions, since the program will not encompass all potentially hazardous pesticides and because EPA did not anticipate program implementation for several years.

Pesticides: EPA Could Do More to Minimize Groundwater Contamination, (GAO/RCED-91-75, Apr. 29, 1991).

Pursuant to a congressional request, GAO examined the Environmental Protection Agency's (EPA) efforts to: (1) assess pesticides' leaching potential in groundwater; (2) regulate those pesticides that could leach into groundwater; and (3) consider human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food. FINDINGS: GAO found that: (1) EPA made limited progress in assessing the leaching potential of the 16 pesticides it identified as groundwater contaminants in 1985; (2) 40 percent of EPA pesticide studies were unacceptable and may have to be redone, and it could be years before EPA has complete data to conduct comprehensive leaching assessments for those pesticides; (3) insufficient resources, staff shortages, low priorities, and ineffective policies addressing the potential for groundwater contamination contributed to the limited progress; (4) the EPA system for tracking data requirements and studies was unreliable; (5) EPA did not fully or consistently utilize the regulatory measures available to reduce groundwater contamination; (6) groundwater contamination was not among the specific criteria in the EPA regulation for initiating special reviews; (7) EPA plans to request that states develop management plans for pesticides that leach into groundwater; and (8) in setting and reviewing tolerances for pesticide residues in food, EPA did not routinely consider human exposure resulting from pesticides in groundwater.

Pesticides: EPA's Use of Benefit Assessments in Regulating Pesticides (GAO/RCED-91-52, Mar. 7, 1991).

Pursuant to a congressional request, GAO reviewed the Environmental Protection Agency's (EPA) practices for considering the benefits of food-use pesticides, focusing on the: (1) EPA definition and quantification of the benefits of food-use pesticides; and (2) the role of benefit assessment in EPA tolerance and registration decisions. FINDINGS: GAO found that EPA: (1) considered the value of increased crop yields attributable to the use of one chemical pesticide over another as the primary measure of pesticide benefits; (2) performed a biological analysis to determine such benefits as enhanced crop yields and quality, and an economic analysis to express the biological benefits in dollar terms; (3) used partial budgeting and agricultural modeling to formally estimate the economic benefits of pesticides; (4) based initial tolerance-setting and registration decisions primarily on potential risks to human health and to the environment; (5) formally estimated and compared pesticide benefits and risks during its special review process; (6) also assessed benefits when it suspended a pesticide's registration on an emergency basis, and when it granted exemptions or waivers from standard registration requirements; and (7) derived its regulatory powers over pesticide registration and tolerances from the Food, Drug and Cosmetic Act and the Insecticide, Fungicide and Rodenticide Act.

Disinfectants: Concerns Over the Integrity of EPA's Data Bases (GAO/RCED-90-232, Sept. 21, 1990).

Pursuant to a congressional request, GAO provided information on the Environmental Protection Agency's (EPA) pesticide and disinfectant data systems, focusing on: (1) the Pesticide Product Information System (PPIS); (2) the Pesticide Document Management System (PDMS); and (3) the Federal Insecticide, Fungicide, and Rodenticide Act and Toxic Substances Control Act Enforcement System (FATES). FINDINGS: GAO found that: (1) key data on disinfectants were inaccurate, incomplete, or missing; (2) PPIS had inaccurate data on the number of disinfectants registered to kill tuberculosis bacteria; (3) EPA did not know the extent to which pesticide data in the systems were inaccurate or incomplete, but estimated that it could be in the 60-percent range; (4) EPA lacked adequate procedures for ensuring that data were accurately coded and entered into the system and for ensuring that data remained current; (5) PDMS was missing some data on disinfectant efficacy studies that registrants submitted to EPA between January 1, 1985, and June 26, 1989; (6) FATES did not include production data for some disinfectants; (7) although EPA intended some of the elements in the systems to include the same data, there were some strong indications that they did not; (8) EPA did not consistently classify and code disinfectants in a way that completely distinguished them from other types of antimicrobial pesticides in the three systems; and (9) EPA plans to improve the systems did not address data integrity.

Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, Jul. 23, 1990).

Pursuant to a congressional request, GAO reviewed the Department of Agriculture's (USDA) management and coordination of water quality activities. FINDINGS: GAO found that: (1) USDA developed a water quality initiative for fiscal year 1990 to expand its ongoing water quality programs and establish new programs; (2) 10 USDA agencies are involved in water quality activities and plan to spend $155 million this year; (3) USDA expects the initiative to be more comprehensive and better coordinated than its previous water quality activities; (4) groundwater contamination is a critical issue, since groundwater is the major source of water for many Americans; (5) the agricultural sector is the largest user of pesticides and fertilizers, and these chemicals are increasingly being found in surface water and groundwater supplies; (6) the public increasingly perceives that farm chemicals found in groundwater threaten human health and that limiting their use is warranted; (7) the USDA Low-Input Sustainable Agriculture Program (LISA) offers research grants to promote agricultural production methods that reduce the use of agricultural chemicals and protect the environment; and (8) USDA has not developed a comprehensive departmental policy on water quality.

Lawn Care Pesticide Risks Remain Uncertain While Prohibited Safety Claims Continue (GAO/T-RCED-90-53, Mar. 28, 1990).

GAO discussed: (1) the Environmental Protection Agency's (EPA) progress in reassessing the health risks of common lawn care pesticides; (2) information the pesticide industry provides to the public on product safety; and (3) federal enforcement actions taken against prohibited pesticide safety advertising claims. GAO noted that: (1) EPA has not fully reassessed the health risks of commonly used lawn care pesticides; (2) EPA subjected six pesticides to special review because of concerns about their chronic health and environmental effects; (3) EPA prohibited many uses of and imposed new labelling requirements for diazinon, the most popular lawn care pesticide; (4) EPA took few formal enforcement actions against unacceptable pesticide safety advertising claims; (5) neither the Federal Trade Commission (FTC) nor EPA knew how many improper advertising cases EPA had referred to FTC; (6) FTC rarely initiated action against improper advertising claims, and FTC preferred to defer to EPA in such matters because of its statutory authority and greater expertise; and (7) professional lawn care pesticide applicators were making claims that could discourage users from following safety guidelines and could lead consumers to believe that certain pesticides were safe or nontoxic.

Five Latin American Countries' Controls Over the Registration and Use of Pesticides, (GAO/T-RCED-90-57, Mar. 28, 1990).

GAO discussed five foreign governments' regulatory controls over the registration and use of pesticides. GAO found that: (1) each of the five countries had laws and regulations controlling pesticide availability and use; (2) government monitoring and enforcement activities in all of the countries except one were generally limited; and (3) resource constraints limited the governments' ability to obtain information on U.S. pesticide requirements and disseminate it to export growers. GAO also found that each country: (1) prohibited registration for pesticides that the Environmental Protection Agency (EPA) cancelled or suspended; (2) required registrants to submit a certificate of free sale from the country of origin stating that the pesticide was legal for use; (3) used international maximum residue limits to establish the amount of acceptable pesticide residue on foods; (4) provided for reregistration reviews and procedures to revoke registration when adverse health, safety, or environmental factors became known; and (5) experienced no-tolerance violations on produce exported to the United States because U.S. tolerances had not been established for those specific crops.

Lawn Care Pesticides: Risks Remain Uncertain While Prohibited Safety Claims Continue (GAO/RCED-90-134, Mar. 23, 1990).

Pursuant to a congressional request, GAO reviewed: (1) the information that manufacturers, distributors, and professional applicators of lawn-care pesticides provided to the public about product safety; (2) federal enforcement actions taken against unacceptable advertising claims; and (3) the reregistration status of 34 widely used lawn-care pesticides. FINDINGS: GAO found that: (1) the lawn-care pesticides industry made prohibited product safety claims that differed substantially from claims the Environmental Protection Agency (EPA) allowed as part of product registration; (2) EPA cited limited resources and its focus on product misuse as reasons for assigning a lower enforcement priority to such false and misleading claims; (3) EPA lacked an effective program for monitoring pesticide manufacturers' and distributors' compliance with registration requirements; (4) although the Federal Trade Commission (FTC) had authority to act against false and misleading safety advertising, it preferred to defer to EPA in such matters because of its expertise and legislative authority; (5) FTC believed that EPA was informally handling professional applicators' safety advertising, although EPA lacked authority to do so; (6) EPA remained at a preliminary stage in reassessing the risks of lawn-care pesticides under its registration program; and (7) EPA had not completely reassessed any of the 32 older lawn-care pesticides that were subject to reregistration.

Food Safety and Quality: Five Countries' Efforts to Meet U.S. Requirements on Imported Produce (GAO/RCED-90-55, Mar. 22, 1990).

Pursuant to a congressional request, GAO reviewed: (1) government and private-sector pesticide controls over exported fresh produce in five countries; (2) federal agencies' efforts to help foreign countries improve their pesticide registration and practices; and (3) U.S., state, and private industry responsibilities in monitoring imported produce. FINDINGS: GAO found that: (1) the foreign governments' pesticide registration practices affected the presence and composition of pesticide residues on their exported produce; (2) the foreign governments allowed the use of 110 registered pesticides that did not have Environmental Protection Agency-established tolerance levels; (3) like the United States, the foreign governments did not design their food safety and quality systems to meet other countries' import requirements, but rather to address domestic needs and issues; (4) exporting countries faced many varied pesticide requirements; (5) some countries' export sectors tried to use management practices that considered U.S. pesticide residue requirements; (6) the Uruguay Round of Negotiations on the General Agreement on Tariffs and Trade included proposals to harmonize food safety and sanitary requirements as a way to reduce their use as technical trade barriers; and (7) several U.S. agencies and international organizations provided assistance related to pesticide use to developing countries.

Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food (GAO/T-RCED-89-35, May 17, 1989).

GAO discussed the Environmental Protection Agency's (EPA) methods for assessing potential risks of pesticide residues in food. GAO found that: (1) EPA used its Tolerance Assessment System to estimate dietary exposure to pesticide residues, but it did not establish a policy to assess tolerance levels on population subgroups with the highest potential exposure to pesticides; (2) EPA developed separate cancer risk estimates for the overall U.S. population, even though population subgroup exposure was higher in some cases; and (3) although EPA used residue data in assessments over a 2-year period, there were no guidelines for performing anticipated residue studies. GAO believes that: (1) consideration of all available information on cancer risks would increase the credibility of EPA regulatory decisions on carcinogenic pesticides; and (2) EPA should reevaluate the adequacy of anticipated residue data.

Reregistration and Tolerance Reassessment Remain Incomplete for Most Pesticides (GAO/T-RCED-89-40, May 15, 1989).

GAO discussed the Environmental Protection Agency's (EPA) progress in reregistering pesticides and reassessing pesticide tolerances. GAO found that: (1) despite some progress, EPA was still at a preliminary stage in assessing the risks of older pesticides; (2) EPA has not completely assessed any of the 822 pesticides subject to reregistration; (3) as of December 24, 1988, EPA had issued 194 preliminary assessments; and (4) EPA has completed tolerance reassessments for only 4 of the approximately 387 food-use pesticides subject to reregistration and has completed all tolerance actions for 3 of those 4 pesticides. GAO also found that EPA needs to: (1) establish procedures for reregistering individual products; (2) keep its final regulatory assessments current because of the dynamic nature of pesticide regulation; and (3) enforce label requirements imposed through interim registration standards.

Export of Unregistered Pesticides Is Not Adequately Monitored by EPA (GAO/T-RCED-89-31, May 3, 1989).

GAO discussed the Environmental Protection Agency's (EPA) procedures for monitoring exports of unregistered pesticides and notifying foreign governments of U.S. actions taken on some pesticides. GAO noted that EPA: (1) did not have a program for monitoring pesticide manufacturers' compliance with export notification requirements; (2) did not require export notices for unregistered pesticides which were similar to registered pesticides in composition and use; (3) lacked adequate procedures for preparing and issuing notices to foreign governments when it took significant action on a pesticide because of a serious health or environmental concern; and (4) had not updated a 1985 booklet that summarized and clarified its actions on cancelled, suspended, and restricted pesticides.

Pesticides: Export of Unregistered Pesticides Is Not Adequately Monitored by EPA (GAO/RCED-89-128, Apr. 25, 1989).

In response to a congressional request, GAO reviewed the Environmental Protection Agency's (EPA) implementation of the Federal Insecticide, Fungicide, and Rodenticide Act's (FIFRA) provisions regarding pesticide notification requirements. FINDINGS: GAO found that: (1) EPA lacked an effective program to monitor pesticide manufacturers' compliance with pesticide export notification requirements; (2) pesticide notices did not include sufficient and meaningful information for foreign governments to adequately identify pesticide products; (3) the EPA policy of exempting unregistered pesticide products because of their similarity and use hindered its efforts to monitor pesticide manufacturers' compliance with the notification requirements; (4) EPA received notices from about 26 percent of companies that exported 80 percent of unregistered pesticide products to the United States; (5) EPA lacked internal procedures for preparing and issuing notices to foreign countries and international organizations regarding significant action on individual pesticides; and (6) an EPA booklet on cancelled, suspended, or restricted pesticides was outdated, and foreign governments lacked current pesticide guidelines.

Pesticides: Economic Research Service's Analyses of Proposed EPA Actions (GAO/RCED-89-75BR, Mar. 14, 1989).

In response to a congressional request, GAO reviewed the Economic Research Service's (ERS) activities during fiscal years 1985 through 1988, focusing on: (1) how ERS analyzed the Environmental Protection Agency's (EPA) pesticide regulatory proposals; (2) cost of ERS analyzing the EPA proposals and purposes for which ERS used the funds; (3) the number of proposals ERS analyzed; and (4) the impact on EPA of ERS analysis and comments. FINDINGS: GAO found that: (1) ERS conducted its pesticide analyses as part of the Department of Agriculture's (USDA) National Agricultural Pesticide Impact Assessment Program (NAPIAP); (2) ERS conducted independent studies on water quality, pesticides, and nonpesticide proposals affecting agriculture; (3) NAPIAP, in conjunction with agricultural experts, scientists, and universities, developed and analyzed information on pesticide use, and assessed EPA pesticide regulations' impact on agriculture and the environment; (4) ERS evaluated the economic impact on producers and consumers of EPA-proposed pesticide regulations; (5) in fiscal years 1985 through 1988, ERS spent about $550,000 to $650,000 annually on data base development, economic modelling, and analyses related to EPA pesticide regulations; (6) NAPIAP commented on all 15 EPA proposals to change or cancel certain pesticides; (7) ERS responded to only 7 of 15 EPA pesticide regulations because it felt that the pesticides were not agriculture-related, or because NAPIAP did not assemble an assessment team; (8) ERS and NAPIAP analyses did not impact EPA proposals for three of the four pesticides GAO reviewed, but provided useful comments and limited analytical efforts for three pesticides, and contributed valuable and timely data for one pesticide; and (9) EPA officials believed that ERS pesticide analysis had been objective, and that the agencies' employees regularly communicated informally on pesticides and other matters.

H.R. 3504: Pesticide Monitoring Improvements Act (GAO/T-RCED-88-12, Dec. 14, 1987).

GAO discussed proposed legislation which would require the Food and Drug Administration (FDA) to periodically monitor imported foods for pesticide contamination. GAO found that FDA: (1) did not periodically sample foods imported from countries that regularly exported to the United States; (2) has not conducted an overall analysis to determine what gaps exist in its monitoring and sampling procedures; and (3) lacks adequate information about the types of pesticides foreign countries use on foods. GAO believes that FDA should: (1) require importers to identify the pesticides used on food they import into the United States; and (2) exchange information with foreign countries on pesticides. GAO also believes that the proposed legislation would enhance FDA ability to monitor imported foods for pesticide violations.

Federal Reregistration of Pesticides and Reassessment of Tolerances Will Extend Into the 21st Century (GAO/T-RCED-87-27, June 8, 1987).

GAO discussed the Environmental Protection Agency's (EPA) regulation of pesticides. GAO noted that: (1) EPA has not carried out its congressional mandate to completely reassess the risks of all registered pesticides; (2) until EPA completes its reassessment, it cannot ensure that the public and the environment are protected from dangerous pesticides; (3) EPA registers pesticides and sets tolerances for food pesticide content; (4) after initial delays in the reassessment, Congress authorized EPA to determine the safety of pesticide chemicals, rather than individual pesticide products; (5) EPA reassessment efforts have included a telephone program to gather missing information on pesticide effects, an initiative to develop a regulatory position on each pesticide chemical, and an informal review process to review existing pesticide registrations in the face of new evidence regarding product safety; (6) EPA has only issued two final pesticide registrations; (7) EPA only recently began to assess the effects of pesticide inert ingredients; and (8) EPA resource limitations and the large volume of chemicals to be assessed could delay the reassessment effort's completion by more than 30 years.

Federal Regulation of Pesticide Residues in Food (GAO/T-RCED-87-21, Apr. 30, 1987).

GAO discussed the Environmental Protection Agency's (EPA) and the Food and Drug Administration's (FDA) regulation of pesticide residues in food. FDA is responsible for testing domestic and imported foods for pesticide residues to ensure compliance with EPA residue tolerances. The United States consumes an estimated 290 billion pounds of food each year, of which it imports about 43 billion pounds. GAO found that FDA: (1) cannot detect many pesticides; (2) lacks adequate information on pesticides used on imported crops; (3) does not test all imported foods on a regular basis; (4) generally does not test for pesticides that it cannot detect by the multiresidue method; (5) is unable to prevent the marketing of most adulterated foods because they move very quickly through the marketplace due to their perishability; and (6) is not authorized to issue civil penalties against growers and producers of adulterated foods. GAO also found that EPA: (1) lacks the data for determining safe residue limits and the health hazards of inert pesticides in groundwater; (2) plans to reassess tolerances for 390 older pesticides, but cannot ensure that established residue limits adequately protect health; and (3) has not set tolerance levels for inert pesticide ingredients. GAO believes that the uncertain health risks associated with chemical residues in food underlie the importance of effective food monitoring programs.

Pesticides: Need To Enhance FDA's Ability To Protect the Public From Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986).

In response to a congressional request, GAO reviewed the Food and Drug Administration's (FDA) activities to protect the public from exposure to illegal pesticide residues in the domestic food supply under the Food, Drug, and Cosmetic Act, specifically its: (1) monitoring of the nation's domestic food supply for illegal residues; and (2) efforts to prevent food containing illegal residues from reaching the market. FINDINGS: GAO noted that, since FDA could not monitor all food that might contain illegal pesticide residues, it designed its monitoring program to selectively spot-check a very small amount of domestically produced food and remove food that it found to contain illegal residues. GAO found that the FDA pesticide monitoring program has two major shortcomings because FDA does not: (1) regularly test food for a large number of pesticides that might be present in food, including a number of pesticides that, according to FDA, require continuous or periodic monitoring because they are known as potential health hazards and are likely to be used; (2) prevent the marketing of most of the food that contains illegal pesticide residues; and (3) penalize growers who market food with illegal pesticide residues when FDA is unable to remove it from the market.

Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

Pursuant to a congressional request, GAO reviewed the Food and Drug Administration's (FDA) efforts to protect the public from exposure to illegal pesticide residues in imported food. FINDINGS: GAO found that: (1) the FDA pesticide monitoring program provides limited protection against public exposure to illegal residues in food; (2) FDA samples less than 1 percent of 1 million imported food shipments annually; (3) FDA inspectors at various ports of entry decide the extent to which they apply sample criteria; and (4) FDA uses five multi-residue tests that individually detect many pesticides on a single sample; however, FDA laboratories normally use only one method for each sample. GAO also found that: (1) although FDA policy requires importers to maintain all sampled shipments intact until FDA determines that the product is residue-free, FDA permits importers to release the majority of sampled shipments to U.S. markets before they spoil; (2) of 164 adulterated samples, 73 were not recovered before public consumption; and (3) there were only eight documented cases where FDA assessed importers damages when adulterated food reached the marketplace.

Pesticides: FDA's Investigation of Imported Apple Juice Concentrate (GAO/RCED-86-214-FS, Aug. 29, 1986).

In response to a congressional request, GAO provided information on: (1) the volume of apple juice concentrate the United States imports; and (2) the methodology and testing results of the Food and Drug Administration's (FDA) special investigation on these concentrates. FINDINGS: GAO found that: (1) apple juice concentrate comprises nearly all of the apple juice imports entering the United States; (2) the volume of apple juice concentrate imports increased fivefold between 1980 and 1985; (3) between March and May 1985, FDA district offices sampled each shipment of imported apple juice concentrate for mercury and daminozide, in addition to their regular tests, since there were allegations that these chemicals were present in the concentrate; (4) most samples tested contained no detectable chemical residues; (5) samples containing the chemicals had levels well below the allowable levels; (6) FDA believes that imported apple juice and apple juice concentrate are safe; and (7) FDA added distilled water to its samples so that it could test the samples on a consistent basis and in the form in which they are normally consumed.

Pesticides: EPA's Formidable Task To Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986).

In response to a congressional request, GAO reviewed the Environmental Protection Agency's (EPA) assessment and regulation process for the health and environmental effects of pesticides. FINDINGS: GAO noted that EPA: (1) has not received test and evaluation data on the adverse health and environmental effects of most of the currently registered pesticide products; (2) may conduct a special review to determine the risks and benefits of potentially hazardous pesticides to decide if regulatory action to cancel or restrict the pesticides is needed; and (3) is responsible for determining the maximum amount of pesticide residue that can be safely left in foods, the risks of the inert ingredients that propel, dilute, or stabilize the active ingredients, and the cancer-causing potential of pesticides. GAO found that EPA: (1) will continue its reassessment and reregistration efforts into the next century because of the magnitude and complexity of the tasks involved; (2) is implementing changes to speed up its special review process; (3) is experiencing difficulty in obtaining test data on the effects of some inert ingredients; and (4) has encountered legal inconsistencies with respect to the allowable uses of cancer-causing pesticides in variable situations.

Nonagricultural Pesticides: Risks and Regulation (GAO/RCED-86-97, Apr. 18, 1986).

In response to congressional requests, GAO reported on the Environmental Protection Agency's (EPA) efforts to determine the: (1) risks associated with the use of nonagricultural pesticides; (2) extent of public information concerning such risks; and (3) requirements for professional pesticide applicators to protect the public from misuse. FINDINGS: The chronic health risks associated with nonagricultural pesticides are uncertain because EPA has not reassessed them in accordance with current standards. GAO found that EPA: (1) as of September 30, 1985, had done preliminary assessments on 18 of the 50 chemicals and found that, for 17, it did not have enough chronic toxicity data to complete the assessments; and (2) does not plan to require chronic toxicity testing of all nonagricultural chemicals because it believes that exposure to some pesticides is not significant enough to cause chronic effects in humans, regardless of their toxicity. Environmental groups believe that pesticide labels should state that chronic health risks have not been fully assessed, so that the public can make better choices about pesticide use. However, industry representatives oppose public disclosure because they fear adverse economic effects. The Insecticide, Fungicide, and Rodenticide Act authorizes EPA to take enforcement action against pesticide manufacturers' claims that pesticides are safe, but EPA has taken few such actions. The Federal Trade Commission (FTC), under its authorizing legislation, can act against distributor and applicator claims, but FTC believes that EPA is better able to handle such claims, because of its expertise and specific legislative authority.

United States
Environmental Protection
Agency

Food and Drug
Administration

United States
Department of
Agriculture

ADMINISTRATION PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS: EXECUTIVE SUMMARY OF TESTIMONY

Last June, the Administration announced its commitment to reducing pesticide use and promoting sustainable agriculture through the development of legislative, regulatory, and administrative initiatives. Today, we are pleased to have the opportunity to present the results of our efforts to date.

The Administration's initiatives are designed to maintain and enhance food safety for all Americans, to address recommendations of a 1993 National Academy of Sciences (NAS) report on ways to improve pesticide regulation to better assure that children are fully protected from pesticide risks, and to strengthen regulatory agencies' ability to make and enforce sound, timely, science-based decisions to protect public health and the environment.

The Administration's pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food. Existing residue tolerances would have to be reviewed and brought into conformity with the new safety standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

The principles that guided our work in developing legislative and regulatory proposals included:

- a firm commitment to reducing risks to people and the environment that may be associated with pesticides, and especially to providing greater assurance of protection for children, while ensuring the availability of cost-effective pest management techniques;
- recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of higher-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices;

- implementation of regulatory reforms and incentives for the development of pesticides that will eliminate or reduce risks.

Building on the recommendations of the NAS report and the input we have received from representatives of all interests concerned about pesticide use and regulation, we have developed a comprehensive set of legislative reforms we believe will allow us to make real progress in enhancing public health and environmental protection. Consistent with the approach of the National Performance Review, these changes will make government work better, and establish a more credible pesticide regulatory system that is based on sound science and is capable of acting promptly to reduce pesticide risks whenever they are identified.

The major elements of our reforms are outlined briefly below. Our formal testimony provides more detail on how these provisions would work and the benefits we expect from their implementation. In addition, the testimony gives an update on our progress in addressing the NAS report recommendations and developing pesticide use reduction strategies.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

- **TOLERANCE SETTING**
  Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. For carcinogens this standard represents an upper-bound risk of 1 in one million over a lifetime, calculated using conservative risk assessment methods.

  The statute would mandate use of the best available science and information in decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, however, conservative or "worst case" default assumptions would be required.

  The statute would also specify criteria for the types of factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations.

- **SPECIAL PROVISIONS FOR INFANTS AND CHILDREN**

  Our proposals for tolerance setting are directly responsive to the NAS recommendations that EPA consider unique aspects of children's diets and other sources of pesticide exposure. EPA would be required to issue specific findings that a tolerance is safe for infants and children.

EPA would also follow the NAS recommendations of looking at multiple exposures when establishing a tolerance and vigorously pursuing more accurate data on children's consumption habits. FDA would prioritize monitoring of residues on the foods children eat most.

- **REVIEW OF EXISTING TOLERANCES**
  EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment.

  Special fast track provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of these tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment.

- **TIME-LIMITED TRANSITIONAL TOLERANCES**

  In exceptional cases, EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, if the loss of the pesticide would result in significant disruption in the food supply.

  Under no circumstances would such time-limited tolerances be granted for pesticide risks that exceed ten times negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to negligible and the continuing existence of the effects that warranted the initial extension of the tolerance.

  A greater than a time-limited tolerance extended under these provisions could only be renewed if Congress enacted a statutory exemption.

  Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerance setting be health-based, and that risk assessments incorporate improved toxicology and exposure data.

IMPROVED REGULATORY COORDINATION AND NEW ENFORCEMENT TOOLS

Both FIFRA and FFDCA should explicitly recognize and require that changes made to one statute should be reconciled with complimentary action under the other statute for issues relating to pesticide use on food. Additionally, FDA should have enhanced enforcement authorities to recall and embargo violative foods as well as to levy civil penalties, and have access to certain pesticide-related records.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS

o **REGISTRATION "SUNSET"**

Pesticide registrations and tolerances must be renewed every 15 years to ensure they are in conformity with health standards. This will apply unless a new application meeting current scientific standards is received by year 12 after registration and approved by EPA.

o **PHASE-OUT/PHASE-DOWN**

Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements.

o **STREAMLINING LABEL CHANGES AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE ("LABEL CALL-IN")**
Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

o **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**
EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided in FIFRA.

Also, EPA would be authorized to grant special time-limited conditional registrations for biologically-based pesticides posing low potential risks.

- **PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT**
  The Administration is calling for a joint EPA-USDA chaired effort to, within one year, develop commodity-specific pesticide use reduction goals.

  The statute would state a clear policy goal favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

  The statute would authorize regional ecosystem-based reduced use pilot projects and set a goal for development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment. EPA and USDA would be mandated to work together to identify the research, education and extension activities that are most promising in terms of opportunities for reducing dependence on pesticide use, in particular targeting pesticides that raise risk concerns.

  The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

  EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

- **IMPROVED PESTICIDE DATA COLLECTION**
  Following the model of the 1990 Farm Bill provisions, which requires record keeping for restricted use pesticides, the Administration calls for record-keeping on all pesticide uses.

  EPA and HHS will continue to pursue better incident monitoring and surveillance systems.

- **PESTICIDE MINOR USES**
  Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

  EPA, HHS/PHS, and USDA would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with

HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

- **CANCELLATION, SUSPENSION, AND TOLERANCE REVOCATION PROCEDURES**

  Cancellation and tolerance revocation procedures would be amended to replace formal, trial-type ALJ proceedings with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

- **ENFORCEMENT AUTHORITIES**

  Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for FIFRA violations, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

- **PREVENTING EXPORT OF PESTICIDES BANNED BY EPA**
  Export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns or those pesticides that were voluntarily canceled in U.S. by the manufacturer for health or safety reasons. Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food.

- **FEES TO SUPPORT FIFRA '88 REREGISTRATION**
  The proposal would include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

September 21, 1993

BOSTON PUBLIC LIBRARY
3 9999 05982 491 0

ISBN 0-16-044229-X

90000

9 780160 442292